

Ashland Inc.

Thomas P. Baker EHS Manager

Ashland Research Center 500 Hercules Road Wilmington, DE 19808-1599 Tel: 302-995-3455, Fax: 302 995-3359 tpbaker@ashland.com

### FEDERAL EXPRESS AND EMAIL

May 17, 2016

State of Delaware – DNREC
Division of Air and Waste Management
State Street Commons
100 W. Water Street, Suite 6A
Dover, DE 19904
Attn: Program Administrator

RE: Submission of Updated Air Quality Permit Applications for the Installation of Four Units that are part of the R & D Spray Drying Process at the Hercules Incorporated Research Center (a.k.a., Ashland Inc.), Wilmington Research Center, 500 Hercules Road, Wilmington, Delaware, Current Permit No. <a href="AQM-003/00017(Renewal1)">AQM-003/00017(Renewal1)</a>; an Air Contaminant Registration Application; and updated site Potential to Emit Calculations

Dear Sir or Madam:

We want to thank the DNREC Air Permit team for meeting with us on May 2, 2016 at the New Castle office to discuss our permit status for the referenced facility. As requested at the meeting, Ashland, Inc. is submitting the following documents to correct and clarify emission information and potential to emit calculations:

- Updated permit applications for the installation of four dryers that are part of the process to be used for R & D
  purposes for the pharmaceutical industry and will consist of the following equipment:
  - One R&D Spray Dryer (closed loop system with internal condenser integral to the process);
  - One GMP Spray Dryer (closed loop system with internal condenser integral to the process);
  - One SD Micro Spray Dryer; and
  - One MP-1 Fluid Bed Drver

The emissions from the four listed units will be controlled by two, 2000 lb. carbon adsorbers in series. We request that each permit reflect the maximum pound per hour emission rate for each individual solvent used at one hundred percent and a total VOC and HAP ton per year emission level based on the typical solvent mixture as provided in the application information.

- 2. An updated AQM-4.2 to request a change from our previously requested carbon bed leak check process, the details of which are included in Section 27.1.
- 3. An Air Contaminant Registration Form and supporting documents for a small dryer (Buchi) in building 8162A.
- 4. An updated site potential to emit spreadsheet incorporating all emission units for the site. All spreadsheets included with the submittal will be included with the electronic submittal.

If you have any questions regarding the information provided herein, please do not hesitate to contact me at 302-995-3455 or via electronic email at tpbaker@ashland.com.

Offine Dele

Thomas P. Baker

Ashland, Inc.

Enclosure

Sincerely

# Administrative Information

Form AQM-1 Page 1 of 5

# **Administrative Information**

One original and one copy of All Application Forms Should Be Mailed To:
Air Quality Management
100 West Water Street, Suite 6A
Dover, DE 19904

All Checks Should Be Made Payable To: State of Delaware

Company and Site Information			
1.	Company Name: Hercules Inc.		
2.	Company Mailing Address: 500 Hercules	Road	
	City: Wilmington	State: <b>DE</b>	Zip Code: <b>19808</b>
3.	Site Name: Ashland Inc. Wilmington Re		
4.	Site Mailing Address: (if different from above)		
	City:	State:	Zip Code:
5.	Physical Location of Site: (if different from above)		29
	City:	State:	Zip Code:
6.	Site Billing Address: (if different from above)		
	City:	State:	Zip Code:
7.	Air Quality Management Facility ID Number: 1000300017		
8.	Site NAICS Code): 541712 (list all that apply		
9.	Site SIC Code: 8731 (list all that apply)		
10.	Site Location Coordinates: Latitude: Longitude:	39.758889 ° '-75.634722 ° '	n
11.	Is the Facility New or Existing?	☐ NEW ☐ EXISTING	
If the	Facility is an Existing Facility, Complete the	Rest of Question 11. If No	ot, Proceed to Question 12.
11.1.	Does the Facility Have Active Air Permits?	YES	□NO
12.	<ul> <li>☐ New Equipment</li> <li>☐ Modification of Existing Equipment</li> <li>☑ Other (Specify): Obtain air permits for three spray dryers and one fluid bed dryer that are all part of the R&amp;D Spray Dryer Process</li> </ul>		
If the application is for the modification of existing equipment, complete the rest of Question 12. If not,			



Form AQM-1 Page 2 of 5

Company and Si	e Information
proceed to Question 13.	
12.1. Does the Equipment Have an Active Air Permit?	☐ YES
If the equipment has an active air permit, complete the re	st of Question 12. If not, proceed to Question 13.
12.2. Permit Number of Existing Equipment: At this to 003/00017 (Renewal-1) and is in the process of	ime the site is operating under Permit AQM- reclassifying as a Natural Minor Source
☐ Synth ☐ Major	al Minor Source etic Minor Source Source ally Enforceable Restrictions
14. Facility Status: 🔲 Natural Minor Facility 🔲 S	ynthetic Minor Facility 🔲 Major Facility
If the facility is a Major Source, complete the rest of Ques	tion 14. If not, proceed to Question 15.
14.1. Responsible Official Name: Michael W. Hassman	
14.2. Responsible Official Title: Director, Facility Serv	ices
Contact Info	ormation
15. Name of Owner or Facility Manager: Michael W. H.	lassman
16. Title of Owner or Facility Manager: Director, Facil	ity Services
17. Permit Contact Name: Thomas P. Baker	
18. Permit Contact Title: EH&S Manager	
19. Permit Contact Telephone Number: 302-995-3455	
20. Permit Contact Fax Number: 302-995-3359	
21. Permit Contact E-Mail Address: tpbaker@ashland	l.com
22. Billing Contact Name: Thomas P. Baker	
23. Billing Contact Title: EH&S Manager	
24. Billing Contact Telephone Number: 302-995-3455	
25. Billing Contact Fax Number: 302-995-3359	
26. Billing Contact E-Mail Address: tpbaker@ashland	l.com
Proposed Construction ar	d Operating Schedule
27. When Will the Proposed Construction/Installation/N	lodification Occur: 09/01/2015
28. Proposed Operating Schedule: 10 hours/day 3.5 da	ys/week <b>52</b> weeks/year
28.1. Is There Any Additional Information Regarding the	Operating Schedule?



Form AQM-1 Page 3 of 5

Proposed Construction and Operating Schedule		
If YES, complete the rest of Question 28. If NO, proceed to Question 29.		
28.2. Describe the Additional Information:		
Coastal Zone Information		
29. Is the Facility Located in the Coastal Zone? 🔲 YES 🔀 NO		
If the facility is located in the Coastal Zone complete the rest of Question 29. If not, proceed to Question 30.		
29.1. Is a Coastal Zone Permit Required for Construction or Operation of the Source Being Applied for?		
Attach a copy of the Coastal Zone Determination if it has not been previously submitted		
If a Coastal Zone Permit is required complete the rest of Question 29. If not, proceed to Question 30.		
29.2. Has a Coastal Zone Permit Been Issued?		
Attach a copy of the Coastal Zone Permit if it has not been previously submitted		
<u>Local Zoning Information</u>		
30. Parcel Zoning: Local zoning approval previously submitted		
Attach Proof of Local Zoning if it has not been previously submitted		
Application Information		
31. Is the Appropriate Application Fee Attached? 🔲 YES 🔀 NO		
32. Is the Advertising Fee Attached?   YES   NO		
For help determining your application and advertising fees see:  http://www.dnrec.state.de.us/DNREC2000/Library/Fees/DE%20Permit%20Fees.htm		
Attach the appropriate fees. Note that your Application will not be considered complete if the appropriate fees are not included.		
33. Is a Cover Letter Describing the Process Attached? XES NO  Attach a brief cover letter describing your Application.		
If the Facility is a New Facility complete Question 34. If not, proceed to Question35.		
34. Is a Copy of the Applicant Background Information ☐ YES ☐ NO Questionnaire on Record at the Department?		
If NO, complete the rest of Question 34. If YES, process to Question 35.		
34.1 Is a Copy of the Applicant Background Information		
For a copy of the Applicant Background Information Questionnaire see <a href="http://www.dnrec.delaware.gov/services/Documents/Chapter79Form.pdf">http://www.dnrec.delaware.gov/services/Documents/Chapter79Form.pdf</a>		
Attach a copy of the Applicant Background Information Questionnaire if applicable.		
35. Check Which Application Forms are Attached:		



Form AQM-1 Page 4 of 5

Application Information		
36. Check Which Documents are Attached:  ☐ Coastal Zone Determination ☐ Coastal Zone Permit ☐ Proof of Local Zoning ☐ Application Fee ☐ Advertising Fee ☐ Applicant Background Information Questionnaire  ☐ Claim of Confidentiality ☐ Manufacturer Specification(s) ☐ Material Safety Data Sheets (MSDSs) ☐ Supporting Calculations ☐ Descriptive Cover Letter ☐ Other (Specify): Application and Advertising ☐ Fees were submitted with the original application		
Confidentiality Information		
37. Do You Consider Any of the Information Submitted With this Application Confidential?  For help on how to submit a confidentiality claim see <a href="http://regulations.delaware.gov/register/december2011/final/15%20DE%20Reg%20864%2012-01-11.htm">http://regulations.delaware.gov/register/december2011/final/15%20DE%20Reg%20864%2012-01-11.htm</a> If a Claim of Confidentiality is made it MUST meet the requirements of Section 6 of DNREC's Freedom of Information ("FOIA") Regulation at the time the Application is submitted.		
Signature Block		
I, the undersigned, hereby certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all of its attachments as to the truth, accuracy, and completeness of this information. I certify based on information and belief formed after reasonable inquiry, the statements and information in this document are true, accurate, and complete. By signing this form, I certify that I have not changed, altered, or deleted any portions of this application. I acknowledge that I cannot commence construction, alteration, modification or initiate operation until I receive written approval (i.e. permit, registration, or exemption letter) from the Department. I acknowledge that I may be required to perform testing of the equipment to receive construction or operation approval, and that if I do not receive approval to construct or operate that I may appeal the decision.  Michael W. Hassman  Owner or Operator  Signature of Owner or Operator		

Form AQM-1 Page 5 of 5

All Checks Should Be Made Payable To: State of Delaware Process
Flow
Diagrams



# DNREC - Air Quality Management Section Application to Construct, Operate, or Modify Stationary Sources

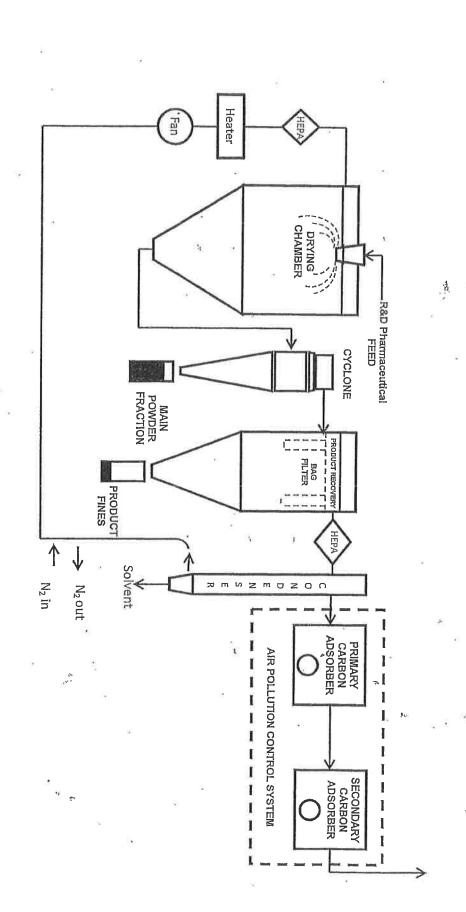
Form AQM-2 Page 1 of 1

# **Process Flow Diagram**

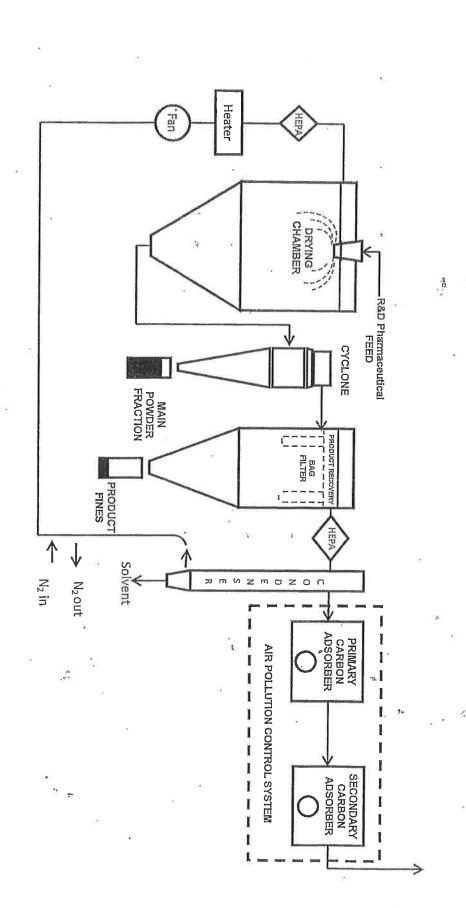
(even existing emission units that will not be modified by this application). You may identify each emission unit with a simple shape. http://www.delaware.gov/reg2/default.htm for example Process Flow Diagrams for common processes. If you already have a Process control device by drawing arrows between them to indicate the flow of air pollutants. List which application forms are included for Sketch the Process Flow Diagram for the equipment or process being applied for. Include each emission unit and control device Label each emission unit and control device with a unique identifier. Show the relationship between each emission unit and/or Flow Diagram for the equipment or process being applied for, you may attach it to the application instead of using this form. each emission unit or control device below the shape representing each emission unit or control device. See

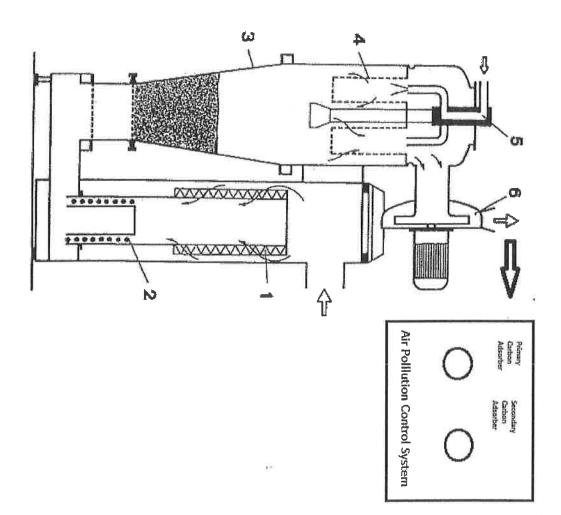
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# Process Flow Diagram for Co-Current Atomizer Spray Dryers:



# Process Flow Diagram for Co-Current Atomizer Spray Dryers:





The principle of the fluid bed dryer consists in bringing flowable moist material like granules or powders to a liquid-like fluidized state by means of an upward heated air stream thus achieving a rapid and careful drying to the desired residual humidity.

The air necessary for this working process is

The air necessary for this working process is sucked in by a fan (6) from outside, cleaned

in the filter housing (1) and heated to the desired temperature in the air heater (2). The prepared air then flows upwards through the material in the product container (3) and absorbs the moisture of the product in the shortest possible time. Dust particles, carried along by the air stream, are held back in the exhaust air filter (4) and continuosusly reconveyed into the fluid bed zone by the filter blow-back device (5),

# R&D PSD-1 Spray Dryer



Form AQM-3.1 Page 1 of 6

# **Generic Process Equipment Application**

If you are using this form electronically, press F1 at any time for help					
	General Information				
1.	Facility Name: Hercules / Ashland Research Center				
2.	Equipment ID Number:	R&D PSD-1 Spray Dryer			
3.	3. Provide a brief description of Equipment or Process: Small co-current atomized nozzle spray dryer for pharmaceutical research. The spray drying system includes a feed pump to pump the feed solution to the atomizer, an inlet gas heater to heat the process gas, a drying chamber to allow for the atomized droplets to contact the hot gas and dry the droplets, a cyclone, a baghouse and a HEPA to collect the product. The solvent evaporated in the drying chamber is recovered in a condenser for reuse/disposal. The uncontolled emissions are vented through two carbon adsorber beds in series.				
4.	Manufacturer: Niro/G	<b>A</b>			
5.	Model:				
6.	Serial Number: 093-19	993-00			
		Raw Material Int	<u>formation</u>		
7.	Raw Materials Used in				
If ther		terials used, attach additional copi	200 * A C 400 C 00 00 0000		
	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?	
7.1.	Active pharmaceuticals and excipients	N/A	Varies	☐ YES 🖾 NO	
7.2.	Ethanol	64-17-5	1986 kg/yr average	☐ YES 🖾 NO	
7.3.	Methanol	67-56-1	4088 kg/yr average	☐ YES 🛛 NO	
7.4.	Acetone	67-64-1	4088 kg/yr average	☐ YES 🖾 NO	
Attacl Attacl	n a copy of a <u>ll</u> calculations m	ade to support the data in the table t (MSDS) for <u>each</u> Raw Material use	above.		
		Products Produced	Information		
8.	Products Produced				
If ther	e are more than four Produc	ts Produced, attach additional copi	es of this page as needed.		
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?	
8.1.	R&D pharmaceuticals	N/A	Various	☐ YES ☒ NO	
8.2.				☐ YES ☐ NO	

Form AQM-3.1 Page 1a of 6

# **Generic Process Equipment Application**

If you are using this form electronically, press F1 at any time for help

	General Information
1.	Facility Name: Hercules / Ashland Research Center
2.	Equipment ID Number: R&D PSD-1 Spray Dryer – Additional Raw Material information
3.	Provide a brief description of Equipment or Process: Small co-current atomized nozzle spray dryer for pharmaceutical research. The spray drying system includes a feed pump to pump the feed solution to the atomizer, an inlet gas heater to heat the process gas, a drying chamber to allow for the atomized droplets to contact the hot gas and dry the droplets, a cyclone, a baghouse and a HEPA to collect the product. The solvent evaporated in the drying chamber is recovered in a condenser for reuse/disposal. The uncontrolled emissions are vented through two carbon adsorber beds in series.
4.	Manufacturer: Niro/GEA
5.	Model:
6.	Serial Number: 093-1993-00

Raw Material Information			
7. Raw Materials Used i	n Process		
If there are more than four Raw N	laterials used, attach addition	nal copies of this page as needed.	
Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1. Isopropanol	67-63-0	117 kg/yr average	YES X NO
7.2. Ethyl Acetate	141-78-6	117 kg/yr average	YES X NO
7.3. Methylene Chloride	75-09-2	1168 kg/yr average	YES X NO
7.4. Tetrahydrofuran	109-99-9	117 kg/yr average	YES X NO

Products Produced Information					
8.	Products Produced				
If the	If there are more than four Products Produced, attach additional copies of this page as needed.				
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?	
8.1.				☐YES ☐NO	
8.2.				☐YES ☐NO	



Form AQM-3.1 Page 2 of 6

Products Produced Information				
8.3.				☐ YES ☐ NO
8.4.				☐ YES ☐ NO
		nade to support the data in the		
Attac	h a Material Safety Data Shee	et (MSDS) for <u>each</u> Product Pr	oduced.	
		Byproducts Gen	erated Information	
9.	Byproducts Generated			
If the	e are more than four Byprod	ucts Generated, attach additi	onal copies of this page as needed	
	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?
9.1.			*	⊠ YES □ NO
9.2.				YES NO
9.3.				☐ YES ☐ NO
9.4.				☐ YES ☐ NO
		nade to support the data in the et (MSDS) for <u>each</u> Byproduct		8
Allaci	l a Material Galety Data Gilot	t (MODO) for <u>cash</u> Dyproduct	Constitution	
		General I	nformation	
10. Manufacturer's Rated Capacity or Maximum Throughput of Equipment or Process: Maximum run rate cannot exceed 4 kg/hr				
11. Describe Important Manufacturer Specifications and/or Operating Parameters for Equipment or Process: See attached				
Attac	n the Manufacturer's Specific	cation Sheet(s) for the equipm	nent or process.	
	WANTE OF THE PARTY	92 N 10 10 10 10		
		Control Devi	ce Information	
12.	Is an Air Pollution Cont		☑ YES ☐ NO	
If an Air Pollution Control Device is used, complete the rest of Question 12. If not, proceed to Question 13.				
	Is Knockout Used?		☐ YES ⊠ NO	
		and attach it to this application		
	Is a Settling Chamber	Used? and attach it to this application	☐ YES ☒ NO	
			n. ☐ YES ☒ NO	
12.3.		ad attach it to this application		
	Is a Fabric Collector or		YES ⊠ NO	



Form AQM-3.1 Page 3 of 6

Control Device Information			
If YES, complete Form AQM-4.6 and attach it to this application.			
12.5. Is a Venturi Scrubber Used?	☐ YES ☑ NO		
If YES, complete Form AQM-4.8 and attach it to this application.			
12.6. Is an Electrostatic Precipitator Used?	☐ YES 図 NO		
If YES, complete Form AQM-4.7 and attach it to this application.			
12.7. Is Adsorption Equipment Used?	⊠ YES □ NO		
If YES, complete Form AQM-4.2 and attach it to this application.			
12.8. Is a Scrubber Used?	☐ YES ☐ NO		
If YES, complete Form AQM-4.4 and attach it to this application.			
12.9. Is a Thermal Oxidizer or Afterburner Used?	☐ YES ☒ NO		
If YES, complete Form AQM-4.1 and attach it to this application.			
12.10. Is a Flare Used?	☐ YES ☐ NO		
If YES, complete Form AQM-4.3 and attach it to this application.			
12.11. Is Any Other Control Device Used?	☐ YES ☐ NO		
If YES, attach a copy of the control device Manufacturer's Specif	ication Sheet(s).		
If any other control device is used, complete the rest of	Question 12. If not, proceed to Question 13.		
12.12. Describe Control Device:			
12.13. Pollutants Controlled: ☐ VOCs ☐ HAPs ☐ PN ☐ Other (Specify):	/I □ PM <sub>10</sub> □ PM <sub>2.5</sub> □ NO <sub>X</sub> □ SO <sub>X</sub> □ Metals		
12.14. Control Device Manufacturer:			
12.15. Control Device Model:			
12.16. Control Device Serial Number:			
12.17. Control Device Design Capacity:			
12.18. Control Device Removal or Destruction Efficiency	y:		
Stack Inf	<u>ormation</u>		
13. How Does the Process Equipment Vent: (check all that apply) ☐ Directly to the Atmosphere ☑ Through a Control Device Covered by Forms AQM-4.1 through 4.12 ☐ Through Another Control Device Described on This Form			
If any of the process equipment vents directly to the atn on this form, proceed to Question 14. If the process eq stack parameters on the control device form and procee	uipment vents through a control device, provide the		
14. Number of Air Contaminant Emission Points: 1			
If there are more than three Emission Points, attach additional co	opies of this page as needed.		
For the first Emission Point			



Form AQM-3.1 Page 4 of 6

Stack Information
15. Emission Point Name: R&D Spray Dryer
15.1. Stack Height Above Grade: 10 feet
15.2. Stack Exit Diameter: 0.333 feet (Provide Stack Dimensions If Rectangular Stack)
15.3. Is a Stack Cap Present? ☐ YES ☒ NO
15.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting (check all that apply) ☐ Other (Specify):
15.5. Stack Exit Gas Temperature: 20 °C
15.6. Stack Exit Gas Flow Rate: 29.7 ACFM
15.7. Distance to Nearest Property Line: 362 feet
15.8. Describe Nearest Obstruction: Building 8162
15.9. Height of Nearest Obstruction: 32 feet
15.10. Distance to Nearest Obstruction: about 10 feet
15.11. Are Stack Sampling Ports Provided? ☐ YES ☒ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.
16. Emission Point Name:
16.1. Stack Height Above Grade: feet
16.2. Stack Exit Diameter: feet (Provide Stack Dimensions If Rectangular Stack)
16.3. Is a Stack Cap Present?
16.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting (check all that apply) ☐ Other (Specify):
16.5. Stack Exit Gas Temperature: °F
16.6. Stack Exit Gas Flow Rate: ACFM
16.7. Distance to Nearest Property Line: feet
16.8. Describe Nearest Obstruction:
16.9. Height of Nearest Obstruction: feet
16.10. Distance to Nearest Obstruction: feet
16.11. Are Stack Sampling Ports Provided?
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.
17. Emission Point Name:
17.1. Stack Height Above Grade: feet
17.2. Stack Exit Diameter: feet (Provide Stack Dimensions if Rectangular Stack)
17.3. Is a Stack Cap Present? YES NO
17.4. Stack Configuration:
17.5. Stack Exit Gas Temperature: °F



Form AQM-3.1 Page 5 of 6

Stack Information
17.6. Stack Exit Gas Flow Rate: ACFM
17.7. Distance to Nearest Property Line: feet
17.8. Describe Nearest Obstruction:
17.9. Height of Nearest Obstruction: feet
17.10. Distance to Nearest Obstruction: feet
17.11. Are Stack Sampling Ports Provided?
Monitoring Information
18. Will Emissions Data be Recorded by a Continuous Emission Monitoring ☐ YES ☒ NO System?
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets
If YES, complete the rest of Question 18. If NO, proceed to Question 19.
18.1. Pollutants Monitored: VOCs HAPs PM PM <sub>10</sub> PM <sub>2.5</sub> NO <sub>X</sub> SO <sub>X</sub> Metals Other (Specify):
18.2. Describe the Continuous Emission Monitoring System:
18.3. Manufacturer:
18.4. Model:
18.5. Serial Number:
18.6. Will Multiple Emission Units Be Monitored at the Same Point?
If YES, complete the rest of Question 18. If NO, proceed to Question 19.
18.7. Emission Units Monitored:
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At YES NO Any Time?
If YES, complete the rest of Question 18. If NO, proceed to Question 19.
18.9. Emission Units Emitting Simultaneously:
Voluntary Emission Limitation Request Information
19. Are You Requesting Any <u>Voluntary Emission Limitations</u> to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, ☐ YES ☒ NO etc.?
If YES, complete the rest of Question 19. If NO, proceed to Question 20.
19.1. Describe Any Requested Emission Limitations:

**Voluntary Operating Limitation Request Information** 



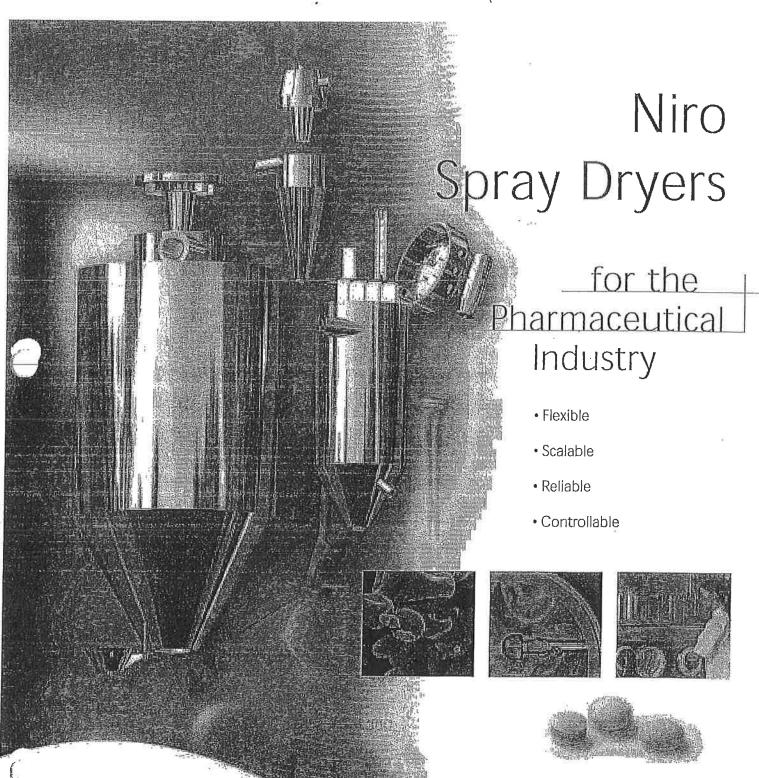
Form AQM-3.1 Page 6 of 6

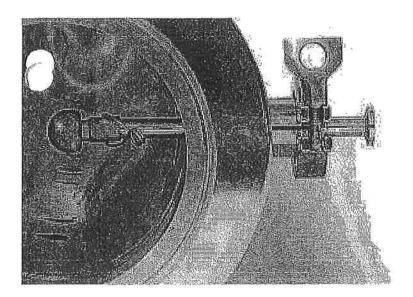
1	Voluntary Operating Limitation Request Inform	<u>nation</u>
20.	Are You Requesting Any Voluntary Operating Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	YES ⊠ NO
If YE.	ES, complete the rest of Question 20. If NO, proceed to Question 21.	
20.1.	. Describe Any Requested Operating Limitations:	
	Additional Information	
21.		s 🛛 NO
		s ⊠ NO
	Is There Any Additional Information Pertinent to this Application? YES, complete the rest of Question 21.	s ⊠ NO
If YES	Is There Any Additional Information Pertinent to this Application? YES, complete the rest of Question 21.	s ⊠ NO

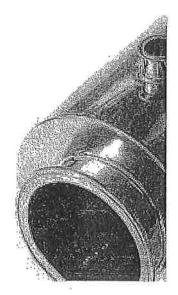


# Niro Pharma Systems

PEROMATIC DICHETTE POT DER MICH MIRO



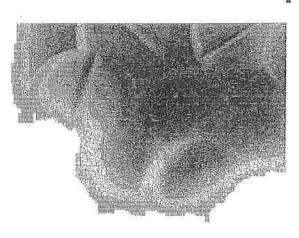




For over half a century, Niro has supplied drying plants for powders and particulates to the pharmaceutical industry. This includes a small capacity dryers designed for R & D as well as industrial size plants for continuous production of pharmaceutical compounds under cGMP conditions.

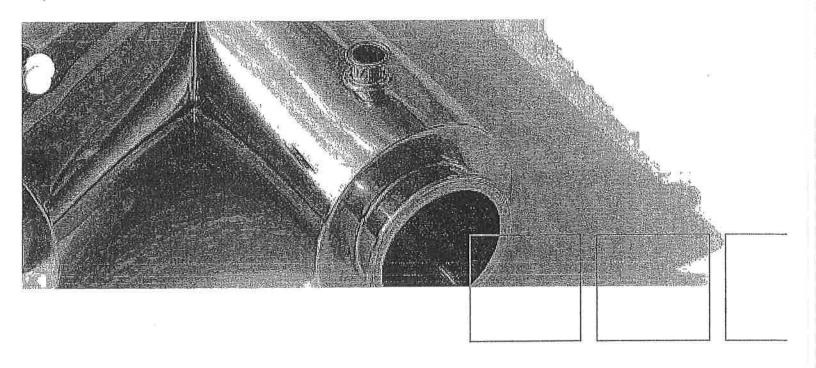
Product Know-How

# Process Expertise



Our plant and process expertise is based on experience and R & D. With plants installed around the world and literally thousands of tests performed, we have established a solid base of expertise related to the needs of the pharmaceutical manufacturing industry.

- 1 2



# Delivering the Right Solutions

Every Niro plant begins with
the customer's desire to create a
product that will succeed in the
market. In Niro, the customer
finds a partner who will assist
him to meet that goal, Our
expertise includes primary as well
as secondary pharmaceuticals,
including technologies for
processing Active Pharmaceutical
Ingredients using spray drying,
agglomeration, encapsulation,
and spray congealing,

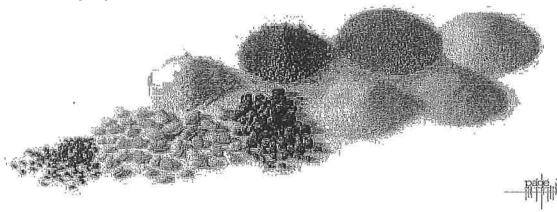
# Plants Customized for Success

Every pharmaceutical plant and system from Niro is a unique union of proven technology and individual solutions. Based on standard components, we supply plants for cGMP production configured to meet the customer's specific requirements.

Among the large number of variations are: The right size to meet the customer's output requirements, the drying principle to be used, atomization configuration, and open or closed cycle operation.

# A Partnership in Every Perspective

Working with Niro means entering a solid partnership every step of the way, from process testing and design to specification of the software controlling your new plant. And our comprehensive after sales program ensures that your return on investment is optimized throughout the lifetime of the plant.



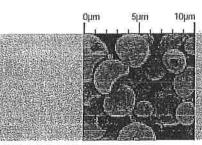
# Primary Pharmaceuticals

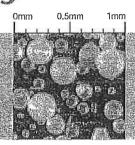
Active Pharmaceutical Ingredients (API) are typically produced by extraction or chemical syntheses. In most cases, the material is subsequently crystallized, mechanically separated, and dried. These steps can often be replaced by spray drying,

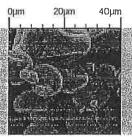
which not only allows the customer to control the moisture or residual solvent content in the powder but also to create materials with a tailor-maid particle size distribution, morphology, and nature.

# Secondary

# Pharmaceuticals







## Powders for Inhalation

Spray drying has become the method of choice for the preparation of fine particles for inhalation. The spray dryer must be equipped with a special atomization device to produce the very fine droplets and a device for fine particle collection.

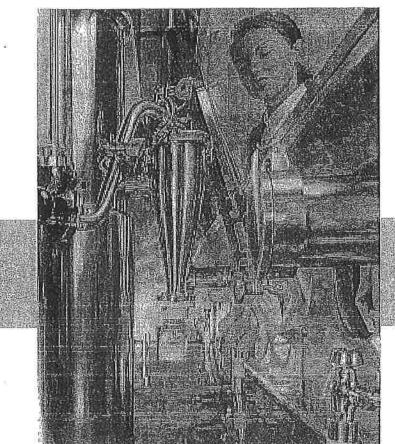
## Encapsulation

One way to achieve a constant drug level in a patient's body is to encapsulate the API in a blodegradable polymer. Controlled by diffusion, the drug is released at a constant rate over a prolonged period of time. To prepare such particles by spray drying, API and polymer are brought into solution and spray dried. Alternatively, spray congealing techniques can be used.

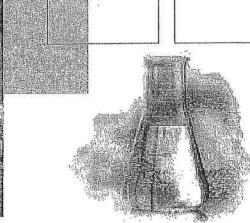
### Increased Bioavailability

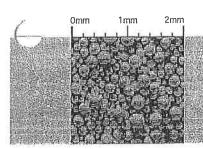
Some modern molecules can have a poor solubility in water or body fluids. Thus it takes an extremely long time for the API crystals to dissolve and for the drug concentration to reach the required level. If the drug product is given orally, the dissolution rate may be increased effectively by keeping the spray dried API in amorphous form using a polymer.

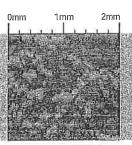




S D Micro<sup>TH</sup> mounted in glove box. Spray dryer for drying very small quantities of feeds containing organic solvents







### **Spray Congealing**

As an alternative to "classic" pharmaceutical production, it is possible to melt the active together with a polymer to enhance bioavailability. As an alternative only the polymer is molten and the active is incorporated just before atomization. The mix is then sprayed into cold process gas. This process can form a matrix in which the release can be easily controlled by the selection of the process conditions without the need for an additional coating step.

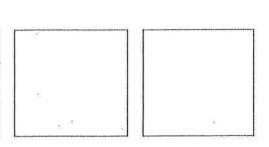
### **Directly Compressible**

Until now, a separate granulation step has often been required in the production of solid dosage forms. The granulate is needed to avoid segregation and to assure flow properties so the dyes of a highspeed tablet press can be filled accurately. With the Fluidized Spray Dryer -  $FSD^{TM}$  or  $IFD^{TM}$  concept the granulation step can be an integrated part of the continuous drying process. The FSD™ technology can also be used to achieve a low residual volatiles content in the final spray dried powder.

### Sterile Excipients

Production of dry sterile dosage forms often involves large-scale mixing of the API with one or more excipients. To achieve a homogeneous mixture, the particle size distribution of the excipient(s) must match that of the API. In a one-step-operation, spray drying can turn a sterile solution of the excipient into sterile particles of the required size with no risk of introducing impurities — a well-known problem if milling is used.





# Spray

Standardized Customization

Today's increased demands for customized design, special materials of construction, special surface treatment, advanced control systems, GMP production, and process validation have resulted in continuous improvement in spray dryer design for the pharmaceutical industry.

Atomization and Powder Discharge

One of the most important choices in a plant configuration is choosing the right atomization and powder discharge method. We offer a wide range of solutions as illustrated below and to the right.

Spray dryer chamber

Swirl cone

Gas/air disperser

Cyclone

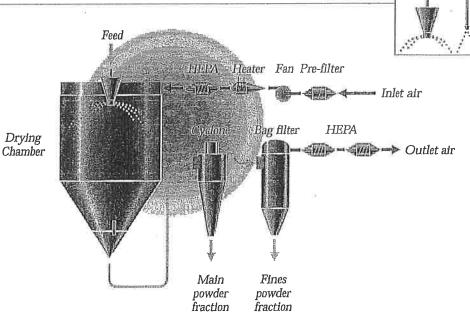
Bag filter

Filter bag cages

Single Point Discharge

Drying

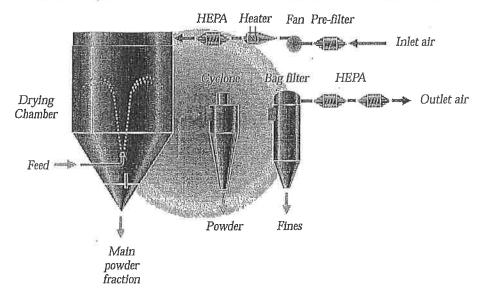
Atomizer/Nozzle Options





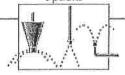
# Two Point Discharge

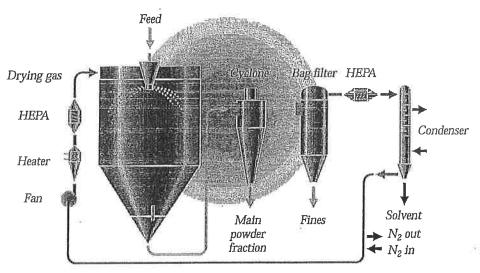
Atomizer/Nozzle
Options



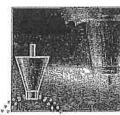
# Closed Cycle Design

Atomizer/Nozzle Options

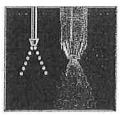




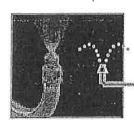
Atomizer/Nozzle Options



Rotary atomizer



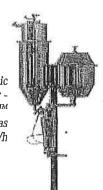
Pressure or two-fluid nozzle, co-current mode



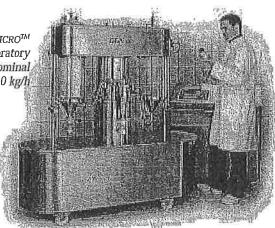
Pressure or two-fluid nozzle, fountain mode



Table top aseptic spray dryer -ASEPTICSSD<sup>TM</sup> Nominal drying gas rate: 30 kg/h



SDMICRO<sup>TM</sup>
R&D and laboratory
spray dryer. Nominal
drying gas rate: 30 kg/h



# PHARMASDTM

Meeting Every Requirement

To meet the high requirements from the pharmaceutical industry, Niro has developed a series of spray dryers, the PHARMASD™ (PSD).

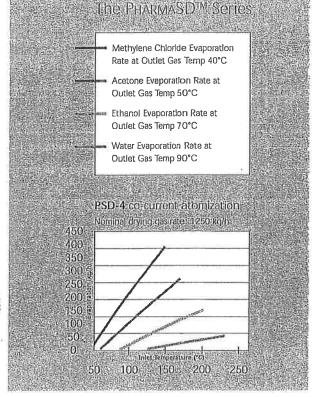
Tailor-Made Standard

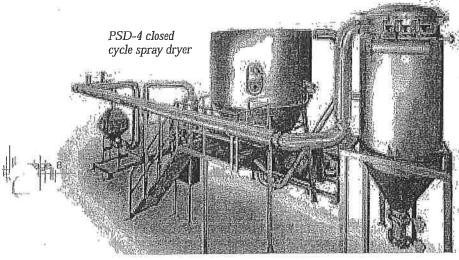
The philosophy behind the design is that a combination of standardized modules are built together in order to meet the requirement for a specific duty. Therefore, dryers of equal capacity may be completely different with respect to design, configuration and physical size.

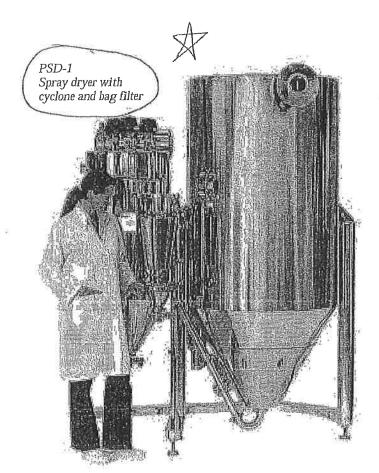
# Spray Drying Organic Solvents

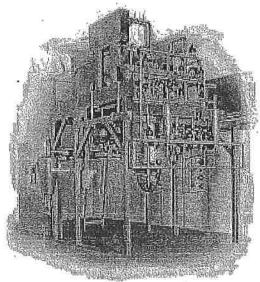
The use of solvents when preparing pharmaceutical ingredients poses a challenge in the drying process and has resulted in the use of nitrogen as a drying gas. Our spray dryers are configured for drying of compounds that are based on acetone,

methylene, chloride, ethanol, and other organic solvents. The drying parameters and capacity vary greatly, depending on the solvent used, as shown in the tables below.

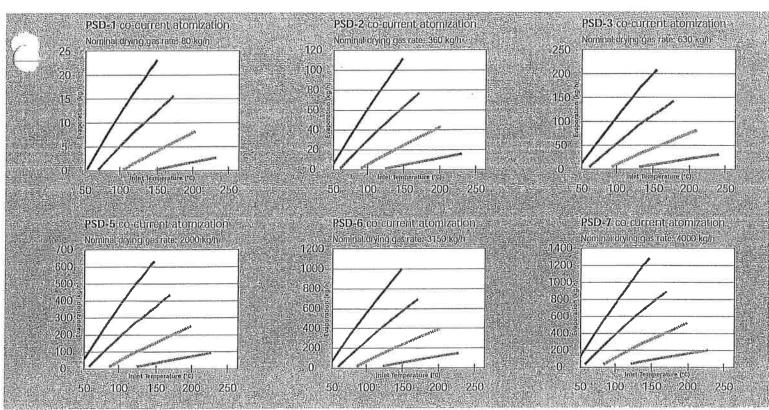




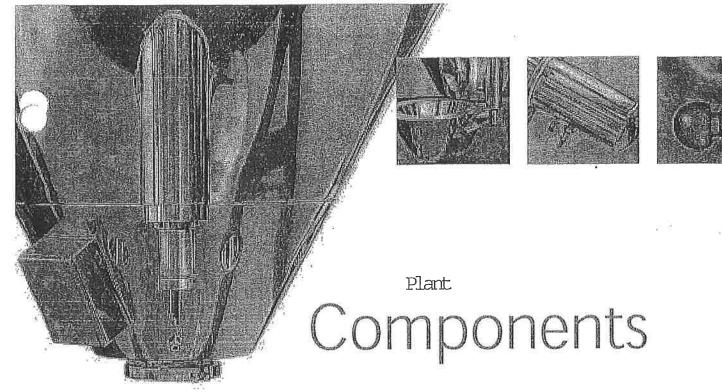


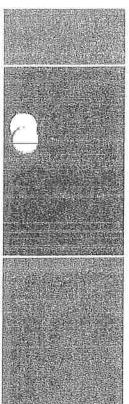


PSD-2 Spray dryer equipped with steam sterilization







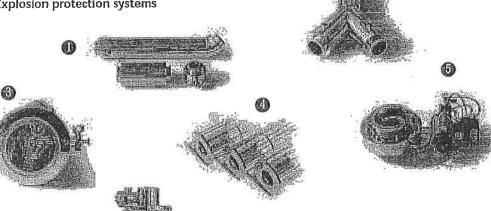


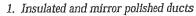
PharmaSD™ design options include:

- Equipment for closed-cycle operation
- Facilities for hot gas sanitization
- Special sanitary duct connections
- Special construction materials
- · HEPA filters for gas streams
- · Special process gas disperser design
- · Swirl cone for chamber access
- · CIP equipment
- · Mirror polished surface
- · Explosion protection systems

Single-unit manufacturing combined with the sue of standard modules has replaced serial plant production withing the pharmaceutical industry, enabling truly customized solutions based on proven systems.

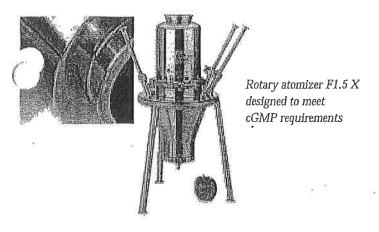
Each module, indeed each system component, must meet the strictest requirements and regulatory standards around the world.





- 2. V-duct with ports for CIP nozzles
- 3. Removable CIP nozzle mounted in duct
- 4. Bag filter cages
- 5. Actuated damper with inflatable sealing
- 6. Insulated cyclone: Ø 140mm



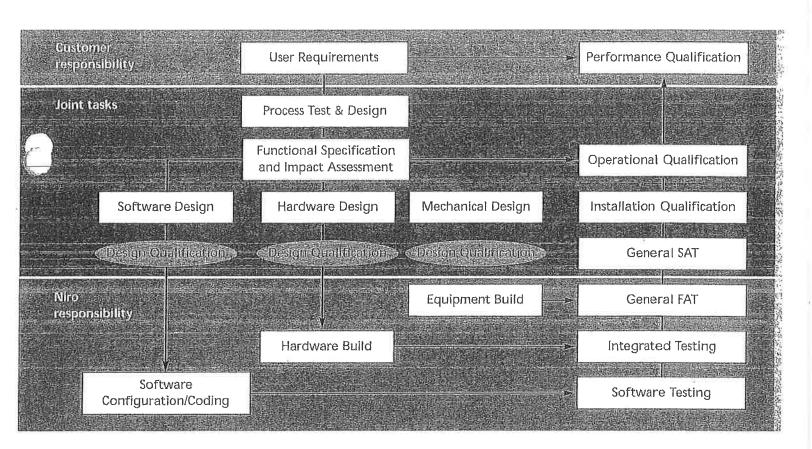


The Complete

# Partnership

### Working with You...

Entering a partnership with Niro means entering a partnership that does not end until you are completely satisfied. From the moment you have specified your user requirements and until the plant has been put into service and has been qualified, our trained staff stays with you at every step of the process, working in close co-operation with your own staff creating the components and systems that will result in a finished plant.



### **Every Step of the Way**

Based on years of experience, equipment qualification will be carried out according to an agreed plan using documents prepared by Niro.

Our engineers will contribute to a successful qualification of the equipment in close co-operation with your validation staff.

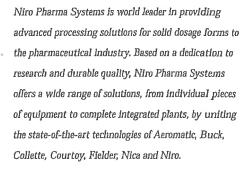


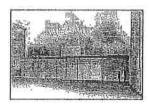
# Niro Pharma Systems



Niro Pharmaceutical **Technology Centre** 

USA: Coating and drying technology





Niro Pharmaceutical **Test Station** 

Denmark: Spray drying technology



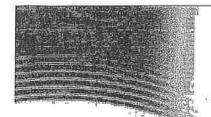
**NPS Technology Center** Switzerland: Solid dosage technology





Niro A/S Denmark

Niro Inc. 9165 Rumsey Road Columbia, MD 21045 Tel: +1 410 997 8700 · Fax: +1 410 997 5021 E-mail: info@.niro.com



WWW, NIROINC, COM



Niro Pharma Systems

Process Engineering

A company of mg technologies group



Niro Inc.

# SPECIFICATION FOR MOBILE MINOR SPRAY DRYER

1. <u>CO-CURRENT TWO-FLUID NOZZLE ATOMIZER</u>, externally mixing, two-fluid nozzle to be mounted in the roof of the drying chamber. The nozzle lance, body, orifice, and air cap are fabricated in stainless steel, type AISI 316. The system is supplied with a 0.5mm orifice, fittings for the air hose connection, air pressure regulator, and air flow meter.

Compressed air must be supplied by the customer at 10 - 50 psig and a maximum of 8 scfm.

- 2. DRYING CHAMBER with an Inside diameter of 0.8 meters and is insulated with approximately 40 mm of Rockwool covered with a stainless steel outer shell. The chamber is provided with an interior light, observation pane for inspection during operation, and one rapping stud. The rapping stud is very useful in applications where sticky materials may attempt to build up in the chamber. The interior is made of stainless steel, type AISI 304. The roof of the drying chamber is made of stainless steel, type AISI 304, inside, and stainless steel, type AISI 304, outside. The entire roof can be lifted, using a special pneumatic lifting device and also tilts for ease of cleaning.
- 3. <u>AIR DISPERSER</u> made of stainless steel, type AISI 304, is built into the roof and specially designed to produce the desired air flow pattern necessary for proper drying of the atomized droplets.
- 4. <u>AIR DUCTS</u> made of stainless steel, type AISI 316, are provided with quick-release threaded fasteners, to ensure easy dismantling for ease of cleaning.
- 5. <u>CYCLONE</u> made of stainless steel, type AISI 316, is designed for maximum collection efficiency and ease of cleaning. The product is collected in a one liter glass jar, threaded to the cyclone discharge.
- 6. <u>EXHAUST FAN</u> made of silumin and is driven by a direct coupled, three (3) phase squirrel cage motor, 0.5 kW. The fan is rated for an air flow of 80 kg/hr (40 cfm).
- 7. AIR HEATER, 10.0 kW, infinitely variable. Maximum inlet air temperature is approximately 350 °C.



- 8. <u>INSTRUMENT PANEL</u> includes Inlet air temperature controller, outlet air temperature indicator, and a switch for starting the fan and obtaining the base load for the electric air heater. The control panel is mounted on a mobile stand with the exhaust fan.
- 9. <u>SUPPORTING STRUCTURE</u> made of stainless steel, type AISI 304, with rubber castors for unit mobility.

# 10. SPARE PARTS

- one set of gaskets for cyclone and air ducts.
- one powder collecting lar.
- one filter for inlet air heater.
- 11. TOOLS for air duct connections.

Electrical Requirements:

230/460 Volt - 3 Ph - 60 Hz

Shipping Volume:

4.0 cubic meters (135 ft)

Gross Weight:

550 kg

Net Weight:

300 kg



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# **Emissions Information Application**

If you are using this form electronically, press F1 at any time for help

		Emissions In	Emissions Information for First Emission Point/Stack	nission Point/Stack		
3.	Emission Point Name: R&D (	R&D Spray Dryer				
4	Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:	rocess Equipment	t and Control Devices Vent	ing Through Emission Poi	1	R&D Spray Dryer
5.	Pollutant Emissions					
If mor	If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.	s Emission Point/Sta	ick, attach additional copies of	this page as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 5.10 through 5.18)	CAS Number (Not required for 5.1 through 5.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
5.1.	Particulate Matter (PM)		0 lbs/hour	lbs/hour	tons/year	tons/year
5.2.	PM <sub>10</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.3.	PM <sub>2.5</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.4.	Sulfur Oxides (SO <sub>X</sub> )		0 lbs/hour	lbs/hour	tons/year	tons/year
5.5.	Nitrogen Oxides (NO <sub>x</sub> )		0 lbs/hour	lbs/hour	tons/year	tons/year
5.6.	Carbon Monoxide (CO)		0 lbs/hour	lbs/hour	tons/year	tons/year
5.7.	Total Volatile Organic Compounds (VOCs)		0.86 lbs/hour	0.09 lbs/hour	1.26 tons/year	0.127 tons/year
5.8.	Total Hazardous Air Pollutants (HAPs)		1.47 lbs/hour	0.15 lbs/hour	2.14 tons/year	0.215 tons/year



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	Emissions	ons Information for First Emission Point/Stack	nission Point/Stack		×
5.9.	CO <sub>2</sub>	0 lbs/hour	lbs/hour	tons/year	tons/year
5.10.	CO <sub>2e</sub>	0 lbs/hour	lbs/hour	tons/year	tons/year
5.11.		lbs/hour	lbs/hour	tons/year	tons/year
5.12.		lbs/hour	lbs/hour	tons/year	tons/year
5.13.		lbs/hour	lbs/hour	tons/year	tons/year
5.14.		lbs/hour	lbs/hour	tons/year	tons/year
5.15.		lbs/hour	lbs/hour	tons/year	tons/year
9.	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	to Understanding the Emissio	on Rates Provided Above:		
Attach ti	Attach the Basis of Determination or Calculations for each Emission Rate provided above.	nission Rate provided above.			

	Ш	Emissions Info	Emissions Information for Second Emission Point/Stack	Emission Point/Stac	וצ	
7.	Emission Point Name:					
ω.	Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:	rocess Equipment	and Control Devices Vent	ling Through Emission Poi	nt/Stack:	
9.	Pollutant Emissions		-			
If more	If more than 15 pollutants are emitted at this Emission		Point/Stack, attach additional copies of this page as needed.	this page as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 9.10 through 9.18)	CAS Number (Not required for 9.1 through 9.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
9.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
9.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
9.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year



Form AQM-5 Page 3 of 8

	E	Emissions Info	ns Information for Second Emission Point/Stack	Emission Point/Stac	ΙŁ	
9.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
9.5.	Nitrogen Oxides (NO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
9.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
9.7.	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
9.8.	Total Hazardous Air Pollutants (HAPs)	0	lbs/hour	lbs/hour	tons/year	tons/year
9.9.	CO <sub>2</sub>		lbs/hour	lbs/hour	tons/year	tons/year
9.10.	CO <sub>2e</sub>		lbs/hour	lbs/hour	tons/year	tons/year
9.11.			lbs/hour	lbs/hour	tons/year	tons/year
9.12.			lbs/hour	lbs/hour	tons/year	tons/year
9.13.			lbs/hour	lbs/hour	tons/year	tons/year
9.14.			lbs/hour	lbs/hour	tons/year	tons/year
9.15.		£	lbs/hour	lbs/hour	tons/year	tons/year
10.	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above	ation Necessary to	Understanding the Emissi	on Rates Provided Above		
Aftach t	Attach the Basis of Determination or Calculations for		each Emission Rate provided above.			

	Emissions Information for Third Emission Point/Stack
11.	11. Emission Point Name:
12.	12. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:
13.	13. Pollutant Emissions
If mor	If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.



Form AQM-5 Page 4 of 8

		Emissions Info	ons Information for Third Emission Point/Stack	mission Point/Stack		
	Pollutant Name (Specify VOCs and HAPs Individually in 13.10 through 13.18)	CAS Number (Not required for 13.1 through 13.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
13.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
13.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
13.5.	Nitrogen Oxides (NO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
13.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
13.7.	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
13.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
13.9.	$CO_2$		lbs/hour	lbs/hour	tons/year	tons/year
13.10.	CO <sub>2e</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.11			lbs/hour	lbs/hour	tons/year	tons/year
13.12.			lbs/hour	lbs/hour	tons/year	tons/year
13.13.			lbs/hour	lbs/hour	tons/year	tons/year
13.14.			lbs/hour	lbs/hour	tons/year	tons/year
13.15.			lbs/hour	lbs/hour	tons/year	tons/year
14.	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	ation Necessary to	Understanding the Emiss	ion Rates Provided Above	*	
Affach t	Attach the Basis of Determination or Calculations for each Emission Rate provided above.	lations for each Emis	sion Rate provided above.			



Form AQM-5 Page 5 of 8

		Emissions Info	Emissions Information for Fourth Emission Point/Stack	mission Point/Stac	٧.	
15.	Emission Point Name:				9	
16.	Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack;	rocess Equipment	and Control Devices Vent	ing Through Emission Pol	int/Stack;	
17.	Pollutant Emissions					
If more	If more than 15 pollutants are emitted at this Emission		Point/Stack, attach additional copies of this page as needed.	this page as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 17.10 through 17.18)	CAS Number (Not required for 17.1 through 17.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Fmissions
17.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
17.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
17.5.	Nitrogen Oxides (NO <sub>x</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
17.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
17.7.	Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
17.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
17.9.	CO <sub>2</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.10.	CO <sub>2e</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.11.			lbs/hour	lbs/hour	tons/year	tons/year
17.12.			lbs/hour	lbs/hour	tons/year	tons/year
17.13.			lbs/hour	lbs/hour	tons/year	tons/year
17.14.			lbs/hour	lbs/hour	tons/year	tons/year
17.15.			lbs/hour	lbs/hour	tons/year	tons/year



Form AQM-5 Page 6 of 8

# **Emissions Information for Fourth Emission Point/Stack**

Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above: 18

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

If there are more than four Emission Points/Stacks, attach additional copies of this form as needed.

## Overall Process Emissions

		-,	Overall Process Emissions	ssions		
19.	Pollutant Emissions					
If more	If more than 15 pollutants are emitted from this Process, attach additional copies of this page as needed.	this Process, attach	additional copies of this page a	as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 19.10 through 19.18)	CAS Number (Not required for 19.1 through 19.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
19.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
19.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
19.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year
19.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
19.5.	Nitrogen Oxides (NO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
19.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
19.7.	Total Volatile Organic Compounds (VOCs)		0.86 lbs/hour	0.09 lbs/hour	1.26 tons/year	0.127 tons/year
19.8.	Total Hazardous Air Pollutants (HAPs)		1.47 lbs/hour	0.15 lbs/hour	2.14 tons/year	0.215 tons/year
19.9.	CO <sub>2</sub>		lbs/hour	lbs/hour	tons/year	tons/year
19.10.	. CO <sub>2e</sub>	).*	lbs/hour	lbs/hour	tons/year	tons/year
19.12.			lbs/hour	lbs/hour	tons/year	tons/year



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		Overall Process Emissions	ssions		
19.13.	3.	lbs/hour	lbs/hour	tons/year	tons/year
19.14	4.	lbs/hour	lbs/hour	tons/year	tons/year
19.15	5.	lbs/hour	lbs/hour	tons/year	tons/year
20.	Provide Any Additional Information N	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	on Rates Provided Above:		
Attac	Attach the Basis of Determination or Calculations for each Emission Rate provided above.	for each Emission Rate provided above.			
		Minor New Source Review Information	Information		
21.	Does the Process Have the Potential to	to Emit More Than Five Tons Per Year of Any Pollutant?		☐ YES ⊠ NO	
22.	Is the Source New or Existing?  See Question 11 of AQM-1	NEW ☐ EXISTING			
If the 1125	If the Process has the Potential to Emit more than five tons per year of any pollutant, and is a New Source, a Control Technology Analysis pursuant to Regulation No. 1125 Section 4 must be conducted and attached to this application.	five tons per year of any pollutant, and is a N o this application.	lew Source, a Control Technold	ogy Analysis pursuant to l	Regulation No.
		Major New Source Review Information	Information		
23.	Does the Process Have the Potential to	I to Emit More Than the Significance Level for Any Pollutant? (Check All That Apply)	evel for Any Pollutant? (Ch	neck All That Apply)	
	Greater Than 25 Tons Per Year of Particulate Matter (PM)  Greater Than 15 Tons Per Year of PM <sub>10</sub> Greater Than 10 Tons Per Year of PM <sub>2.5</sub> Greater Than 40 Tons Per Year of Sulfur Dioxide(SO <sub>2</sub> )  Greater Than 25 Tons Per Year of Nitrogen Oxides (NO <sub>X</sub> )  Greater Than 100 Tons Per Year of Nitrogen Oxides (NO <sub>X</sub> )  Greater Than 100 Tons Per Year of Carbon Monoxide (CC  Greater Than 25 Tons Per Year of Total Volatile Organic Greater Than 50 Tons Per Year of Total Volatile Organic Greater Than 50 Tons Per Year of Total Volatile Organic Greater Than 75,000 Tons Per Year of Equivalent Carbon	Greater Than 25 Tons Per Year of Particulate Matter (PM) Greater Than 15 Tons Per Year of PM <sub>10</sub> Greater Than 10 Tons Per Year of PM <sub>2.5</sub> Greater Than 40 Tons Per Year of Sulfur Dioxide(SO <sub>2</sub> ) Greater Than 40 Tons Per Year of Nitrogen Oxides (NO <sub>x</sub> ) in New Castle and Kent County Greater Than 100 Tons Per Year of Nitrogen Oxides (NO <sub>x</sub> ) in Sussex County Greater Than 100 Tons Per Year of Carbon Monoxide (CO) Greater Than 25 Tons Per Year of Total Volatile Organic Compounds (VOCs) in New Castle and Kent County Greater Than 50 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex County Greater Than 75,000 Tons Per Year of Equivalent Carbon Dioxide (CO <sub>2e</sub> )	e and Kent County county /OCs) in New Castle and M /OCs) in Sussex County	Kent County	



Form AQM-5 Page 8 of 8 If the Process has the Potential to Emit greater than any of the amounts listed above 7 DE Admin. Code 1125 Sections 2 and/or 3 apply. Contact the Department at (302) 323-4542 or (302) 739-9402 for additional information

<u>ormation</u>	☐ YES 図 NO		
Additional Information	24. Is There Any Additional Information Pertinent to this Application?	If YES, complete the rest of Question 24.	

ın rate (1		Ι 4	kg/hr				i		wed 5/17/2016						
Time (2)			hr/batch												_
ent Use			kg/batch/day	-				-							_
		-	-										<b></b>		
erating D	гауз/уг	292	days/yr	_											
vent Spra	av Drind	11680	kg/vr												
	Max. venting gas rate (s)			EN frounc	led to the next	whole value)									
	Operating Hours		hr/yr	Liv (rounc	I TO THE HEAT	Whole velue									-
	Total Gas Vented(*)		kg/yr NITRO	SEN vente	d						Emissic	ns with 100%	of One Solver	it	
		2010.10	NEW TO THE OWNER.												
	(e)		kg/yr Solvent (pre	Solvent Factor <sup>(7)</sup>	Calculated kg/yr	Maxlmum kg/yr exhausted (post	Maximum lb/hr exhausted (post	Maximum tons/year exhausted (post	Annual Emissions as a 12 month rolling period	% Salvanta	kg/yr Solvent (pre	Calculated kg/yr	Max kg/yr exhausted (post	Max lb/hr exhausted (post	Max Ib exhaus (post car
_	Typical Solvent Mix <sup>(9)</sup>	%	condenser)	(kg/kg)	exhausted <sup>(8)</sup>	condenser)	condenser)*	condenser)	(TPY)	Solvent	condenser)	exhausted	condenser)	condenser)	beds
	Ethanol	17.0%	1,985.6	0.04	224.4	224.4	0.169	0.247	0.025	100%	11680 11680	1,320.0 2,224.8	1,320.0 2,224.8	0.995 1.676	0
	Methanol	35.0%	4,088.0	0.06	778.7	778.7 11.0	0.587	0.857	0.001	100%	11680	1,104.6	1,104.6	0.832	0
	IPA	1,0%	116,8	0.03	11.0 50.0	50.0	0.008	0,012	0.001	100%	11680	5,004.5	5,004.5	3.771	0
	Ethy Acetate	1.0%	116.8	0.14	1,427.2	1,168.0	0.880	1.285	0.128	100%	11680	14,271.9	11,680.0	8.800	0
	Methylene Chloride	1.0%	1,168.0	0.41	77.3	77.3	0,880	0.085	0.128	100%	11680	7,733.8	7,733.8	5.827	0
	THF Acetone	35.0%	4,088.0	0.22	3,375.3	3,375.3	2.543	3,713	0.371	100%	11680	9,643.8	9,643.8	7.266	0
_	Acetone	65%	7,592.0	0.28	2,568.7	2,309.5	1,740	2.540	0.126 VOCs	100%	1,000	3,043.0	3,043.0	7.2.00	-
		65%	7,592,0		2,300.7	2,303.3	*1 kg = 2.2 lb	2.340	0.214 HAPs						-
	NOTES:						1 VK - 5'5 ID		U.E.L. TIATS						
- 2	(1) Based on equipment d	torion the	may run rata	connot ev	cood A kulbe to	mically it is eun:	t 2 kg/by to nce	duce quality r	natorial	_					
						er It all solvent :					_				
2 2 2	(4) Approximately 20% of pray dried material need morphology. The max run (5) MAXIMUM GAS VENTI - The vent rate of each 1.25 kg /hr bag house (it would modulate in c Thus, maximum vent ra- Note: this is the require Solvent vapor in the ve	the time is to be changed days ING RATE: PSD1 drye pulse clea compensa ate after the drye content of the d	throughout the aracterized for is thus calcular is up to 9.5 kining, and 1 kg tion for low /note condenser to rate for non-cours is in additional to the condenser to the condenser to the condenser to the condenser to the for non-count is in additional to the condenser to the co	e year betwood particle so ted as following the system of atomizing color max 1 and enable to the 11 to th	ween batches, Ize, particle size ows: (365 days  ing gas (nomlin pressure cont gas). 1.75 kg/hr (rou 2.75 kg/Hr.	the dryer is also e distribution, d *(100%-20%)=2 hally 6.5 kg/hr), rol nded to 12 above n pressure.	not running bee ensity, solvent o 92 days e),	cause the content and						(94)	
55	(4) Approximately 20% of pray dried material need morphology. The max run (5) MAXIMUM GAS VENTI The vent rate of each F 1.25 kg /hr bag house ( it would modulete in c Thus, maximum vent ra - Note: this is the roquire	the time is to be changed days ING RATE: PSD1 drye pulse clea compensa ate after the drye content of the d	throughout the aracterized for is thus calcular is up to 9.5 kining, and 1 kg tion for low /note condenser to rate for non-cours is in additional to the condenser to the condenser to the condenser to the condenser to the for non-count is in additional to the condenser to the co	e year betwood particle so ted as following the system of atomizing color max 1 and enable to the 11 to th	ween batches, Ize, particle size ows: (365 days  ing gas (nomlin pressure cont gas). 1.75 kg/hr (rou 2.75 kg/Hr.	the dryer is also e distribution, d *(100%-20%)=2 hally 6.5 kg/hr), rol nded to 12 above n pressure.	not running bee ensity, solvent o 92 days e),	cause the content and						75.	
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22 2 2 3 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	A) Approximately 20% of pray dried material need morphology. The max run (5) MAXIMUM GAS VENTI The vent rate of each F 1.25 kg /hr bag house ( it would modulate in c Thus, maximum vent m - Note: this is the require Solvent vapor in the ve (5) Ignores purging syster 7) Solvent Factors:  Solvent Solven	the time is to be changed days in the time is to be changed as the changed days in the	throughout the aracterized for is thus calcular is up to 9.5 kining, and 1 kg tion for low /nc nee condenser it rate for non-cum is in addition tory remaining the condenser of the condenser it rate for non-cum is in addition to y remaining the condenser it rate for non-cum is in addition to y remaining the condense it remaining	e year bets r particle s ted as foll g/hr atomi J/hr systen atomizing otel max 1 andenasble in to the 1 ng at end Vapor Pressure @ max cond temp (mmHg)	ween batches, Ize, particle size ows: (365 days zing gas (nomin n pressure cont gas). 1.75 kg/hr (rou a N2 to maintai 1.75 kg/Hr. of batch, which vol % in N2 @ 1.ATM	the dryer is also e distribution, d  *(100%-20%)=2   hally 6.5 kg/hr), rol   nded to 12 above n pressure. Is negligibly sm  Solvent Factor (kg solv/kg N2 vented)	not running bee ensity, solvent o 92 days e),	cause the content and						(4)	
22 2 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	A) Approximately 20% of spray dried material need morphology. The max run (5) MAXIMUM GAS VENTI - The vent rate of each F 1.25 kg /hr bag house ( It would modulate in c Thus, maximum vent reNote: this fithe require Solvent vapor in the ve (6) Ignores purging syster (7) Solvent Factors:  Solvent Ethanol	the time is to be choiced by the best of the choiced by the choice	throughout the aracterized for is thus calcular is up to 9.5 kning, and 1 kgition for low /nc e condenser the rate for non-cum is in addition tory remaining.  Max Cond Temp, C.	e year bets r particle s ted as foll g/hr atomi g/hr system atomizing odolmax 1 andenasble n to the 1 ng at end o  Vapor Pressure @ max cond temp, (mmHg) 17	ween batches, Ize, particle sizo ows: (365 days zing gas (nomin n pressure cont n gas). 1.75 kg/hr (rou a N2 to maintai 1.75 kg/Hr. of batch, which  val % in N2 @ 1 ATM 2.24	the dryer is also e distribution, d *(100%-20%)=2 inally 6.5 kg/hr), rol inded to 12 above a pressure.  Is negligibly sm  Solvent Factor [kg solv/kg N2 vented] 0.038	not running bee ensity, solvent o 92 days e),	cause the content and							
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( ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) (	A) Approximately 20% of pray dried material need morphology. The max run (5) MAXIMUM GAS VENTI - The vent rate of each F 1.25 kg /hr bag house (It would modulate in c Thus, maximum vent re-Note: this is the require Solvent vapor in the ve (6) Ignores purging syster (7) Solvent Factors:  Solvent Ethanol Methanol Acetone IPA Ethy Acetate Methylene Chloride	the time is to be changed agree in the time is the time in the time in the time is the time in the time in the time is the time in the time in time in the time in the time in the time is the time in time in the time in time in the time in time in the time in time in the time in time in the time in t	throughout the aracterized for is thus calcular Is up to 9.5 kining, and 1 kgition for low /nc is condenser is rate for non-comm is in addition nory remaining the formular is condenser is condenser is condenser in a dditton or remaining the formular is condenser in addition or remaining the formular is condenser in addition or remaining the formular is condenser in addition of the formular in a condense i	e year bets r particle s ted as foll g/hr stomi g/hr system atomizing cold max 1 andenable n to the 11 ang at end of Vapor Pressure @ max cond temp. (mmHg) 17 40 89 11 33 90 60	ween batches, ize, particle size ows: (365 days with the size of t	the dryer is also e distribution, d *(100%-20%)=2 mally 6.5 kg/hr), rol medical to 12 above in pressure.  Solvent Factor (kg solv/kg N2 vented) 0.038 0.275 0.032 0.143 0.407 0.221	not running bee ensity, solvent o 92 days e),	cause the content and							
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	4) Approximately 20% of pray dried material need morphology. The max run 5) MAXIMUM GAS VENTI - The vent rate of each F 1.25 kg /hr bag house ( It would modulate in c Thus, maximum vent r - Note: this is the require Solvent vapor in the ve (6) Ignores purging syster 7) Solvent Factors:  Solvent Ethanol Methanol Acetone IPA Ethy Acetate Methylene Chloride THF Condenser temperatures meet desired process an Vapor Pressure Data Ref.	the time is to be changed agree to be changed	throughout the aracterized for is thus calcular is up to 9.5 kining, and 1 kining, and 1 kining in the condenser is the condenser is the condenser is the condenser is the additional interpretable in the condenser is in additional interpretable in the condenser is the condenser is condenser in the condenser in	yapor. Pressure @ max. cond temp. (mmHg) 13 33 90 60 municures of Organs	ween batches, ize, particle size ows: (365 days with the size of t	the dryer is also e distribution, d *(100%-20%)=2 hally 6.5 kg/hr), rol hally 6.5 kg/hr), rol hally 6.5 kg/hr).  Solvent Factor [kg solv/ kg N2 vented] 0.038 0.063 0.275 0.032 0.143 0.407 0.221 cess tc	not running bee ensity, solvent o 92 days e),	cause the content and							

Solvent Used <sup>[1]</sup> Defrating Days/yr <sup>[4]</sup> Solvent Spray Dried  Max. venting gas rate <sup>[5]</sup> Derrating Hours  Total Gas Vented <sup>[6]</sup> 17,5													
ng gas rate <sup>[5]</sup> Hours /ented <sup>(9)</sup>	8.0 hr/batch												
ng gas rate <sup>[S]</sup> Hours /ented <sup>[0]</sup>	16 kg/batch/day												
ing gas rate <sup>[5</sup> ; Hours Vented <sup>(6)</sup>	182.5 days/yr												
ing gas rate <sup>[5]</sup> Hours Vented <sup>[6]</sup>	2920 kg/vr												
[0]	12 kg/hr NITROGEN (round	N (rounded to	led to the next whole value)	(e value)									
(6)	1,460 hr/vr												
	17,520 kg/yr NITROGEN vented	EN vented											
	kg/yr	Solvent	Calculated	Expected kg/yr exhausted	Expected lb/hr exhausted	Expected tons/year		kg/yr Solvent	Calculated	Expected kg/yr exhausted	Expected lb/hr exhausted	Expected Emissions	II.
Typical Solvent Mix <sup>(9)</sup> %	solvent (pre condenser)	(kg/kg)	exhausted <sup>(8)</sup>	(post condenser)	(post condenser)*	exhausted (post condenser)	%	(pre condenser)	kg/yr exhausted	(post condenser)	(post condenser)	(ib/hr) after carbon beds	
		0.04	112.2	112.2	0,169	0.123	100%	2920	660.0	660.0	0.995	0.099	
lon I		90.0	389.3	389.3	0.587	0.428	100%	2920	1,112.4	1,112.4	1,676	0.168	
İ		0.03	č.	J.7.	0.008	0.006	100%	2920	552.3	552.3	0.832	0.083	
Mothirlang Chlade 100 00	1	0.14	25.0	25.0	0.038	0.028	100%	2920	2,502.3	2,502.3	3.771	0.377	
-		0.33	5.135.9	2,920.0	4.400	3.212	3002	2920	7,135.9	2,920.0	4.400	0.440	
Arotono 35 092	25.7	0.72	1,507.7	1,077.0	0.044	1,124	100%	2920	3,866,9	2,920.0	4.400	0.440	
T		07.0	7,706.7	3.481.3	5.246	4.124 3.829	TOUZ	0757	4,621.3	2,920.0	4.400	0.440	
	L			Part of the	*1 kg=22 lh	2000							
NOTES:					21.71.7 - GV 4								
(1) Based on equipment design, the max run rate cannot	n, the max run rat	e cannot exce	ed 4 kg/hr, typ	ically it is run a	t 2 kg/hr to pro	exceed 4 kg/hr, typically it is run at 2 kg/hr to produce quality material.	eriai						
assembly will take at least 14 hours. The actual rub time is typically less than 8 hours. (3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the solids.	= solvent + solids.	To be conser-	pically less than	Tit all solvent a	nd do not adius	t out the solids							
(4) Essethan half of the time the spray drypr will be numine 365 days \$ 5 days	he spray driver wi	The running	365 dave*0.5m	187 5 days	The sound of the s	ייים מוכי מוכי אמותם							
(5) MAXIMUM GAS VENTING RATE:	RATE:	9	Trin cken con	cken make									
- The vent rate of each PSD1 dryer is up to 9.5 kg/hr atomizing gas (naminally 6.5 kg/hr)	1 dryer is up to 9.	5 ka/frr atomiz	ing gas (namir	lally 6.5 kg/hr).									
1.25 kg /hr bag house pulse cleaning, and 1 kg/hr system pressure control	se cleaning, and	karhr system	n pressure cont	io.									
( It would modulate in compensation for low /no atomizing gas).	pensation for low.	no atomizing	gas).										
Thus, maximum vent rate after the condenser total max 11.75 kg/hr (rounded to 12 above)	after the condens	er total max 1	1.75 kg/hr (rou	nded to 12 abo	we).								
- Note: this is the required venting rate for non-condensable N2 to maintain pressure.	enting rate for nor	-condensable	N2 to maintail	n pressure.									
Solvent vapor in the vented stream is in addition to the 11.75 kg/Hr	d stream is In add	lition to the 11	.75 kg/Hr.										
(5) ignores purging system gas inventory remaining at end of batch, which is negligibly small relative to solvent in the vent	s Inventory remai	ning at end or	batch, which i	s negligibly sm.	all relative to so.	vent in the vent							
(7) Solvent Factors:		1/2000											
		Pressure											
		@ max		Solvent				(3)					
Solvent	Max Cond	temp,	Vol % in NZ	(kg solv/									
	L	17	2.24	0.038									
_		40	5,26	0.063									
Acetone 58.10	5 01	89	11.71	0.275									
		11	1.45	0.032									
Ethyl Acetate 88.10		33	4.34	0.143									
de	ľ	96	11.84	0.407									
+-		9	7.89	0.221									
- Condenser temperatures Indicated are the maximum required by the process to	licated are the ma	ximum requir	ed by the proc	ess to									
meet desired process and product specifications.	roduct specification	ins.											
- Vapor Pressure Data Ref: Table 3-8, Vapor Pressures of	ble 3-8. Vapor Pre	ssures of Orga	Organic Compounds, up to	S. up to									
1 ATM, Table 3-8, Vapor Pressures of Organic Compounds, up to 1 Atm	ssures of Organic	Compounds	In to 1 Afm	22 42 62									
Perry's Handbook, 5th ed.													
(8) Calculation assumes are is saturated at indicated maximum assumes	anturated at India	mend manipulation	of respective	-									

R&D Spray Dryer (PSD-1)		W 15	1	Potential To Emit		Expected	Expected Emission	Permi	Permit Limits
<u>Pollutant</u>	<u>XOC7</u>	HAP?	Maximum Uncontrolled Emission Rate Ib/hr(2)	Maximum Controlled Emission Rate	Annual Potential To Emit (PTE) (tons/yr) <sup>(J,(2)</sup>	Expected Annual Uncontrolled Emissions (tons/yr)	Expected Annual Controlled Emissions (tons/vr) <sup>(1)</sup>	Emissions (lb/hr) after carbon beds	Annual Emissions as a 12 month rolling period (TPY)
Ethanol	Yes	No	0.169	0.017	0.247	0.123	0.012	0.099	0.025
Methanol	Yes	Yes	0.587	0.059	0.857	0.428	0.043	0.168	0.086
IPA	Yes	No	0.008	0.001	0.012	90000	0.001	0.083	0:001
Ethyl Acetate	Yes	No	0.038	0.004	0.055	0.028	0.003	0.377	0.006
Methylene Chloride	No	Yes	0.880	0.088	1.285	3.212	0.321	0.880	0.128
Tetrahydrofuran (THF)	Yes	No	0.058	9000	0.085	0.032	0.003	0.583	0:00
Acetone	No	No	2.543	0.254	3.713	1.124	0.112	0.727	0:371
VOC			98.0	60.0	1.26	0.62	90.0	NA	0.126
HAP	14		1.47	0.15	2.14	3.64	0.36	NA	0.214
Notes:									
(1) The controlled emissions assume a carbon adsorption control efficiency of 90%. There are two carbon canisters operating in series, so the	e a carbon a	dsorption	n control efficienc	y of 90%. There	are two carbon	canisters operating in	n series, so the		
actual control efficiency will be greater than 90%.	ater than 90	%:							
(2) Acetone, as defined by the US EPA, is neither a VOC nor a HAP, and the totals are not included in the VOC or HAP totals	PA, is neit	her a VO	C nor a HAP, and	the totals are not	included in the	VOC or HAP totals			

## GMP PSD-1 Spray Dryer



Form AQM-3.1 Page 1 of 6

#### **Generic Process Equipment Application**

	If you are	using this form electronicall	y, press F1 at any time for ne	эр 
		General Infor	mation	
1.	Facility Name: <b>Hercul</b>	es / Ashland Research Cente	er	
2.	Equipment ID Number	: GMP PSD-1 Spray Dryer		
3.	for pharmaceutical re solution to the atomiz for the atomized drop a HEPA to collect the	esearch. The spray drying syzer, an inlet gas heater to he plets to contact the hot gas a product. The solvent evapo disposal. The uncontolled e	Small co-current atomized nystem includes a feed pump at the process gas, a drying and dry the droplets, a cyclor rated in the drying chamber missions are vented through	to pump the feed chamber to allow ne, a baghouse and is recovered in a
4.	Manufacturer: Niro/G	EA		
5.	Model:			
6.	Serial Number:			
		Raw Material Int	formation ————————————————————————————————————	
7.	Raw Materials Used in			
If ther	e are more than four Raw Ma	aterials used, attach additional copi		T
	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1.	Active pharmaceuticals and excipients	N/A	Varies	☐ YES 🖾 NO
7.2.	Ethanol	64-17-5	1986 kg/yr average	☐ YES 🖾 NO
7.3.	Methanol	67-56-1	4088 kg/yr average	☐ YES 🖾 NO
7.4.	Acetone	67-64-1	4088 kg/yr average	☐ YES ☐ NO
Attach Attach	n a copy of a <u>ll</u> calculations m	nade to support the data in the table (MSDS) for <u>each</u> Raw Material use	above.	
		Products Produced	l Information	
8.	Products Produced			
If ther	e are more than four Produc	ts Produced, attach additional copi	es of this page as needed.	
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.	R&D pharmaceuticals	N/A	Various	☐ YES 🖾 NO
8.2.				☐ YES ☐ NO

Form AQM-3.1 Page 1a of 6

#### **Generic Process Equipment Application**

If you are using this form electronically, press F1 at any time for help

	General Information
1.	Facility Name: Hercules / Ashland Research Center
2.	Equipment ID Number: GMP PSD-1 Spray Dryer – Additional Raw Material information
3.	Provide a brief description of Equipment or Process: Small co-current atomized nozzle spray dryer for pharmaceutical research. The spray drying system includes a feed pump to pump the feed solution to the atomizer, an inlet gas heater to heat the process gas, a drying chamber to allow for the atomized droplets to contact the hot gas and dry the droplets, a cyclone, a baghouse and a HEPA to collect the product. The solvent evaporated in the drying chamber is recovered in a condenser for reuse/disposal. The uncontrolled emissions are vented through two carbon adsorber beds in series.
4.	Manufacturer: Niro/GEA
5.	Model:
6.	Serial Number:

	Raw Material	<u>Information</u>	
7. Raw Materials Used i	n Process		
If there are more than four Raw M	Naterials used, attach addition	nal copies of this page as needed.	79
Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1. Isopropanol	67-63-0	117 kg/yr average	YES X NO
7.2. Ethyl Acetate	141-78-6	117 kg/yr average	YES X NO
7.3. Methylene Chloride	75-09-2	1168 kg/yr average	YES X NO
7.4. Tetrahydrofuran	109-99-9	117 kg/yr average	YES X NO

		Products Produced	Information	
8.	Products Produced			
If there	e are more than four Products	s Produced, attach additional copie	s of this page as needed.	
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.			4	☐YES ☐NO
8.2.				☐YES ☐NO



Form AQM-3.1 Page 2 of 6

		Products Pro	oduced Information	
8.3.				☐ YES ☐ NO
8.4.				☐YES ☐NO
Attac	h a copy of a <u>ll</u> calculations n			
Attac	h a Material Safety Data Shee	et (MSDS) for <u>each</u> Produc	ct Produced.	
		Byproducts G	enerated Information	
9.	Byproducts Generated			
			dditional copies of this page as needed.	
ii tirei	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?
9.1.				☑ YES ☐ NO
9.2.				☐ YES ☐ NO
9.3.				☐ YES ☐ NO
9.4.				☐ YES ☐ NO
Attacl	h a copy of a <u>ll</u> calculations m	nade to support the data in	n the table above.	
Attaci	h a Material Safety Data Shee	et (MSDS) for <u>each</u> Byproc	duct Generated.	
		Genera	al Information	
10.	Manufacturer's Rated		Throughput of Equipment or Proces	s: Maximum run rate
12:	cannot exceed 4 kg/h			
11,	Describe Important Ma Process: See attache		ons and/or Operating Parameters for	Equipment or
	Process. See attache	a		
Attacl	h the Manufacturer's Specific	cation Sheet(s) for the equ	uipment or process.	
			evice Information	
12.	Is an Air Pollution Cont		☐ YES ☐ NO	
If an	Air Pollution Control Dev	vice is used, complete	the rest of Question 12. If not, proce	eed to Question 13.
	Is Knockout Used?		☐ YES ☐ NO	
	complete Form AQM-4.11 a		atlon. ☐ YES ⊠ NO	
	Is a Settling Chamber 6, complete Form AQM-4.10 a			
	Is an Inertial or Cyclon		☐ YES ☒ NO	
	6, complete Form AQM-4.5 ar			
	Is a Fabric Collector or		□ YES ⋈ NO	



Form AQM-3.1 Page 3 of 6

Control Device	e Information
If YES, complete Form AQM-4.6 and attach it to this application.	
12.5. Is a Venturi Scrubber Used?	☐ YES ☑ NO
If YES, complete Form AQM-4.8 and attach it to this application.	
12.6. Is an Electrostatic Precipitator Used?	☐ YES ☑ NO
If YES, complete Form AQM-4.7 and attach it to this application.	
12.7. Is Adsorption Equipment Used?	⊠ YES □ NO
If YES, complete Form AQM-4.2 and attach it to this application.	
12.8. Is a Scrubber Used?	☐ YES ☒ NO
If YES, complete Form AQM-4.4 and attach it to this application.	
12.9. Is a Thermal Oxidizer or Afterburner Used?	☐ YES ☒ NO
If YES, complete Form AQM-4.1 and attach it to this application.	
12.10. Is a Flare Used?	☐ YES ⊠ NO
If YES, complete Form AQM-4.3 and attach it to this application.	
12.11. Is Any Other Control Device Used?	☐ YES 🖾 NO
If YES, attach a copy of the control device Manufacturer's Specif	ication Sheet(s).
If any other control device is used, complete the rest of	Question 12. If not, proceed to Question 13.
12.12. Describe Control Device:	4 <sup>2</sup>
12.13. Pollutants Controlled: ☐ VOCs ☐ HAPs ☐ PN ☐ Other (Specify):	/I ☐ PM <sub>10</sub> ☐ PM <sub>2.5</sub> ☐ NO <sub>X</sub> ☐ SO <sub>X</sub> ☐ Metals
12.14. Control Device Manufacturer:	
12.15. Control Device Model:	
12.16. Control Device Serial Number:	
12.17. Control Device Design Capacity:	
12.18. Control Device Removal or Destruction Efficiency	r.
Stack Info	<u>ormation</u>
<ul> <li>How Does the Process Equipment Vent: (check all that apply) ☐ Directly to the Atmosphere</li> <li>Through a Control Device Covered by Forms</li> <li>Through Another Control Device Described or</li> </ul>	n This Form
If any of the process equipment vents directly to the atm on this form, proceed to Question 14. If the process equ stack parameters on the control device form and procee	uipment vents through a control device, provide the
14. Number of Air Contaminant Emission Points: 1	
If there are more than three Emission Points, attach additional co	pies of this page as needed.
For the first Emission Point	



Form AQM-3.1 Page 4 of 6

Stack Information
15. Emission Point Name: GMP Spray Dryer
15.1. Stack Height Above Grade: 10 feet
15.2. Stack Exit Diameter: 0.333 feet (Provide Stack Dimensions If Rectangular Stack)
15.3. Is a Stack Cap Present?
15.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☑ Downward-Venting (check all that apply) ☐ Other (Specify):
15.5. Stack Exit Gas Temperature: 20 °C
15.6. Stack Exit Gas Flow Rate: 29.7 ACFM
15.7. Distance to Nearest Property Line: 362 feet
15.8. Describe Nearest Obstruction: Building 8162
15.9. Height of Nearest Obstruction: 32 feet
15.10. Distance to Nearest Obstruction: about 10 feet
15.11. Are Stack Sampling Ports Provided? ☐ YES ☐ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.
16. Emission Point Name:
16.1. Stack Height Above Grade: feet
16.2. Stack Exit Diameter: feet (Provide Stack Dimensions If Rectangular Stack)
16.3. Is a Stack Cap Present?
16.4. Stack Configuration:  Vertical Horizontal Downward-Venting (check all that apply) Other (Specify):
16.5. Stack Exit Gas Temperature: °F
16.6. Stack Exit Gas Flow Rate: ACFM
16.7. Distance to Nearest Property Line: feet
16.8. Describe Nearest Obstruction:
16.9. Height of Nearest Obstruction: feet
16.10. Distance to Nearest Obstruction: feet
16.11. Are Stack Sampling Ports Provided?
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.
17. Emission Point Name:
17.1. Stack Height Above Grade: feet
17.2. Stack Exit Diameter: feet (Provide Stack Dimensions If Rectangular Stack)
17.3. Is a Stack Cap Present?  YES NO
17.4. Stack Configuration:  Vertical  Horizontal Downward-Venting (check all that apply)  Other (Specify):
17.5. Stack Exit Gas Temperature: °F



Form AQM-3.1 Page 5 of 6

Stack Information
17.6. Stack Exit Gas Flow Rate: ACFM
17.7. Distance to Nearest Property Line; feet
17.8. Describe Nearest Obstruction:
17.9. Height of Nearest Obstruction: feet
17.10. Distance to Nearest Obstruction: feet
17.11. Are Stack Sampling Ports Provided?
Monitoring Information
18. Will Emissions Data be Recorded by a Continuous Emission Monitoring ☐ YES ☒ NO System?
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets
If YES, complete the rest of Question 18. If NO, proceed to Question 19.  18.1. Pollutants Monitored: TVOCs THAPS TPM TPM <sub>10</sub> TPM <sub>2.5</sub> NO <sub>x</sub> SO <sub>x</sub> Metals
18.1. Pollutants Monitored: VOCs HAPs PM PM <sub>10</sub> PM <sub>2.5</sub> NO <sub>X</sub> SO <sub>X</sub> Metals Other (Specify):
18.2. Describe the Continuous Emission Monitoring System:
18.3. Manufacturer:
18.4. Model:
18.5. Serial Number:
18.6. Will Multiple Emission Units Be Monitored at the Same Point? 🔲 YES 🔲 NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.
18.7. Emission Units Monitored:
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At ☐ YES ☐ NO Any Time?
If YES, complete the rest of Question 18. If NO, proceed to Question 19.
18.9. Emission Units Emitting Simultaneously:
Voluntary Emission Limitation Request Information
19. Are You Requesting Any <u>Voluntary Emission Limitations</u> to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, ☐ YES ☒ NO etc.?
If YES, complete the rest of Question 19. If NO, proceed to Question 20.
19.1. Describe Any Requested Emission Limitations:

**Voluntary Operating Limitation Request Information** 



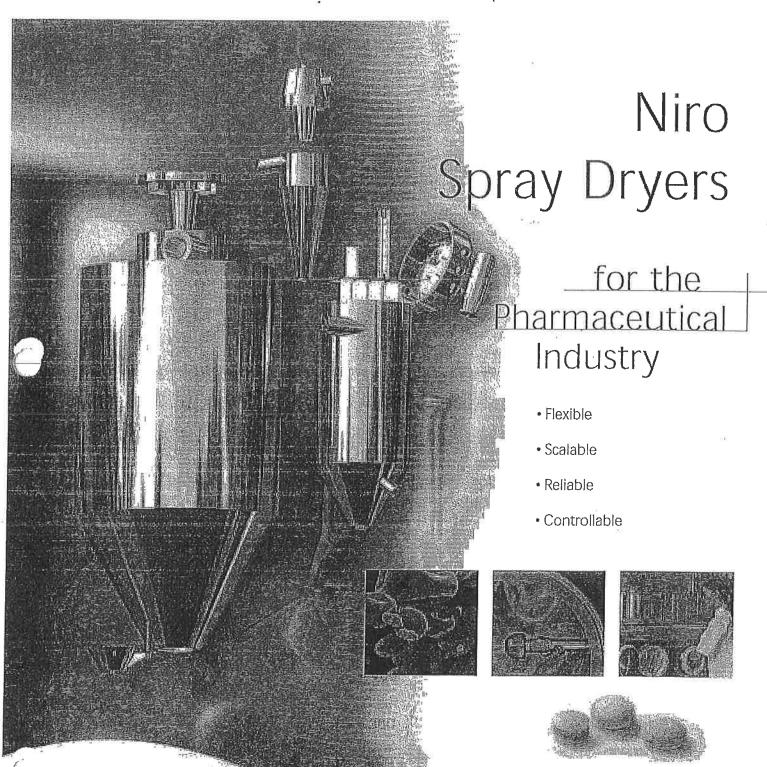
Form AQM-3.1 Page 6 of 6

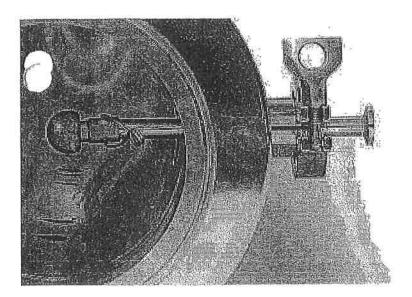
	Voluntary Operating Limitation Reques	<u>t Information</u>
20.	Are You Requesting Any <u>Voluntary Operating Limitations</u> to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ⊠ NO
If YE	S, complete the rest of Question 20. If NO, proceed to Question 21	9
20.1.	Describe Any Requested Operating Limitations:	
l		
	<u>Additional Information</u>	
21.	Is There Any Additional Information Pertinent to this Application?	☐ YES ⊠ NO
If YES	c, complete the rest of Question 21.	
21.1.	Describe:	

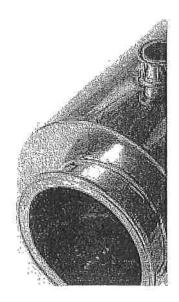


#### Niro Pharma Systems

PEROMATIC SICHETTE POT LELDER VICE VICE VICE VICE VICE VICE VIETO



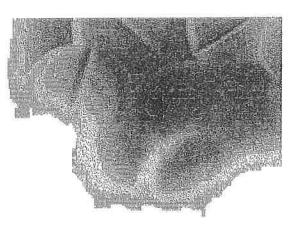




For over half a century, Niro has supplied drying plants for powders and particulates to the pharmaceutical industry. This includes a small capacity dryers designed for R & D as well as industrial size plants for continuous production of pharmaceutical compounds under cGMP conditions.

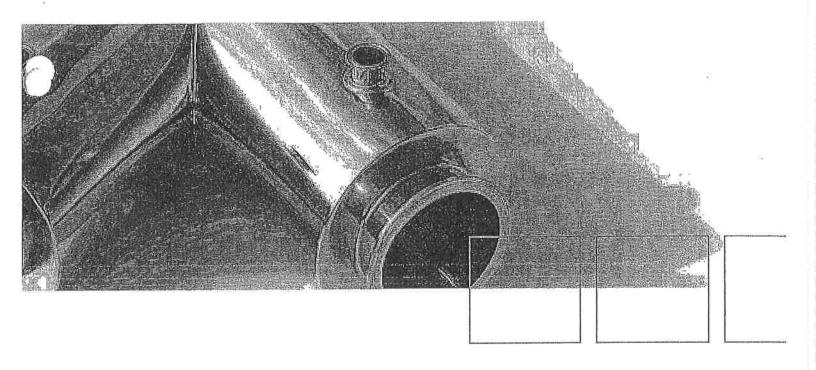
Product Know-How

### Process Expertise



Our plant and process expertise is based on experience and R & D. With plants installed around the world and literally thousands of tests performed, we have established a solid base of expertise related to the needs of the pharmaceutical manufacturing industry.





#### Delivering the Right Solutions

Every Niro plant begins with the customer's desire to create a product that will succeed in the market. In Niro, the customer finds a partner who will assist him to meet that goal. Our expertise includes primary as well as secondary pharmaceuticals, including technologies for processing Active Pharmaceutical Ingredients using spray drying, agglomeration, encapsulation, and spray congealing.

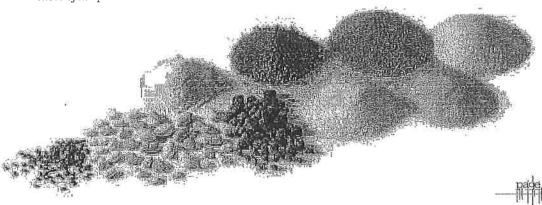
#### Plants Customized for Success

Every pharmaceutical plant and system from Niro is a unique union of proven technology and individual solutions. Based on standard components, we supply plants for cGMP production configured to meet the customer's specific requirements.

Among the large number of variations are: The right size to meet the customer's output requirements, the drying principle to be used, atomization configuration, and open or closed cycle operation.

#### A Partnership in Every Perspective

Working with Niro means entering a solid partnership every step of the way, from process testing and design to specification of the software controlling your new plant. And our comprehensive after sales program ensures that your return on investment is optimized throughout the lifetime of the plant.



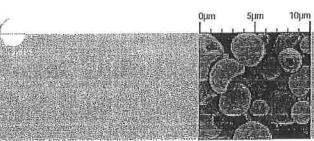
#### Primary Pharmaceuticals

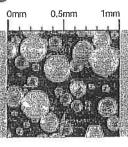
Active Pharmaceutical Ingredients (API) are typically produced by extraction or chemical syntheses. In most cases, the material is subsequently crystallized, mechanically separated, and dried. These steps can often be replaced by spray drying,

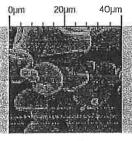
which not only allows the customer to control the moisture or residual solvent content in the powder but also to create materials with a tailor-maid particle size distribution, morphology, and nature.

#### Secondary

#### Pharmaceuticals







#### Powders for Inhalation

Spray drying has become the method of choice for the preparation of fine particles for inhalation. The spray dryer must be equipped with a special atomization device to produce the very fine droplets and a device for fine particle collection.

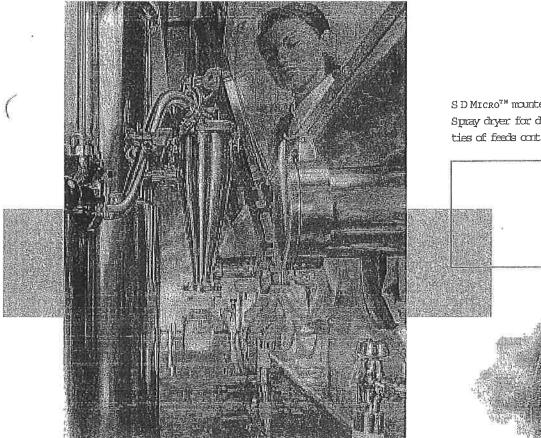
#### Encapsulation

One way to achieve a constant drug level in a patient's body is to encapsulate the API in a biodegradable polymer. Controlled by diffusion, the drug is released at a constant rate over a prolonged period of time. To prepare such particles by spray drying, API and polymer are brought into solution and spray dried. Alternatively, spray congealing techniques can be used.

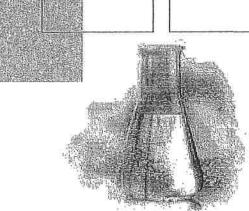
#### Increased Bioavailability

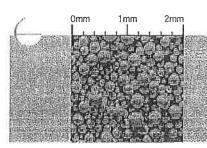
Some modern molecules can have a poor solubility in water or body fluids. Thus it takes an extremely long time for the API crystals to dissolve and for the drug concentration to reach the required level. If the drug product is given orally, the dissolution rate may be increased effectively by keeping the spray dried API in amorphous form using a polymer.

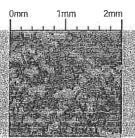




S D Micro \*\* mounted in glove box. Spray dryer for drying very small quantities of feeds containing organic solvents







#### Spray Congealing

As an alternative to "classic" pharmaceutical production, it is possible to melt the active together with a polymer to enhance bioavailability. As an alternative only the polymer is molten and the active is incorporated just before atomization. The mix is then sprayed into cold process gas. This process can form a matrlx in which the release can be easily controlled by the selection of the process conditions without the need for an additional coating step.

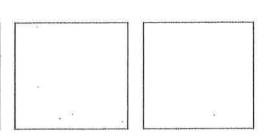
#### **Directly Compressible**

Until now, a separate granulation step has often been required in the production of solid dosage forms. The granulate is needed to avoid segregation and to assure flow properties so the dyes of a highspeed tablet press can be filled accurately. With the Fluidized Spray Dryer -  $FSD^{\rm TM}$  or  $IFD^{\rm TM}$  concept the granulation step can be an integrated part of the continuous drying process. The FSD™ technology can also be used to achieve a low residual volatiles content in the final spray dried powder.

#### Sterile Excipients

Production of dry sterile dosage forms often involves large-scale mixing of the API with one or more excipients. To achieve a homogeneous mixture, the particle size distribution of the excipient(s) must match that of the API. In a one-step-operation, spray drying can turn a sterile solution of the excipient into sterlle particles of the required size with no risk of introducing impurities --- a wellknown problem if milling is used.



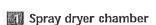


### Spray Drying

Standardized Customization

Today's increased demands for customized design, special materials of construction, special surface treatment, advanced control systems, GMP production, and process validation have resulted in continuous improvement in spray dryer design for the pharmaceutical industry.

Atomization and
Powder Discharge
One of the most important
choices in a plant configuration is choosing the right
atomization and powder
discharge method. We offer
a wide range of solutions
as illustrated below and to
the right.



Swirl cone

Gas/air disperser

**Cyclone** 

Bag filter

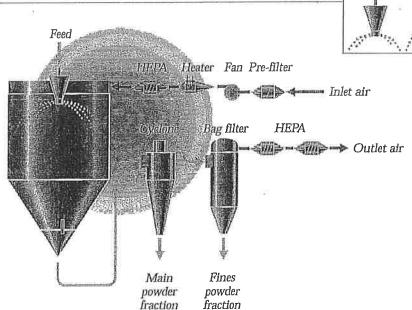
Filter bag cages

Single Point Discharge

Drying

Chamber

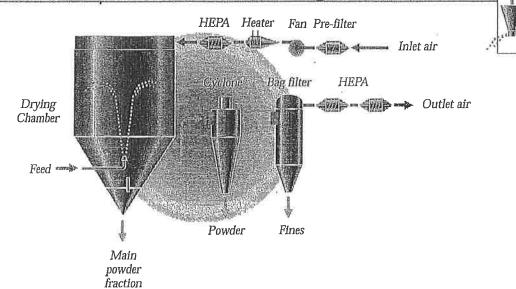
Atomizer/Nozzle Options





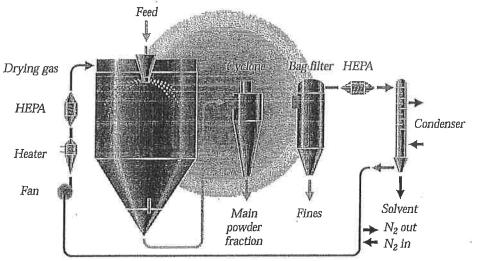
#### Two Point Discharge

Atomizer/Nozzle Options

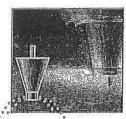


#### Closed Cycle Design

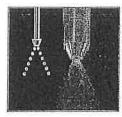
Atomizer/Nozzle Options



Atomizer/Nozzle Options



Rotary atomizer



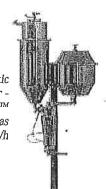
Pressure or two-fluid nozzle, co-current mode



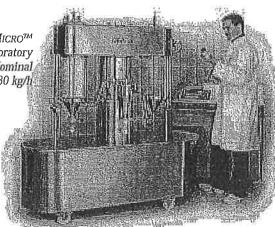
Pressure or two-fluid nozzle, fountain mode



Table top aseptic spray dryer -ASEPTICSSD™ Nominal drying gas rate: 30 kg/h



SDMICRO™ R&D and laboratory spray dryer. Nominal drying gas rate: 30 kg/h



#### PHARMASDTM

Meeting Every Requirement

To meet the high requirements from the pharmaceutical industry, Niro has developed a series of spray dryers, the PHARMASD™ (PSD).

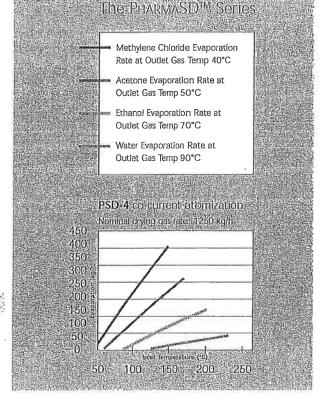
Tailor-Made Standard

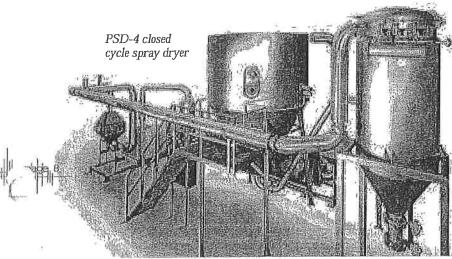
The philosophy behind the design is that a combination of standardized modules are built together in order to meet the requirement for a specific duty. Therefore, dryers of equal capacity may be completely different with respect to design, configuration and physical size.

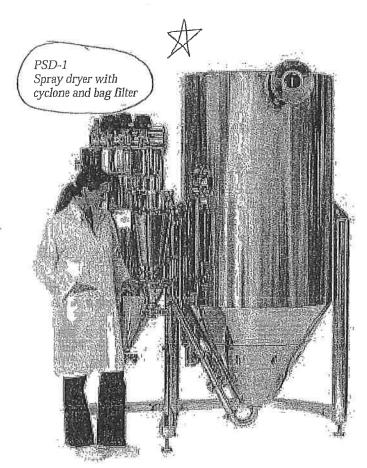
Spray Drying Organic Solvents

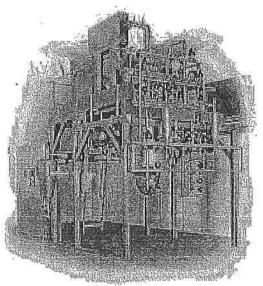
The use of solvents when preparing pharmaceutical ingredients poses a challenge in the drying process and has resulted in the use of nitrogen as a drying gas. Our spray dryers are configured for drying of compounds that are based on acetone,

methylene, chloride, ethanol, and other organic solvents. The drying parameters and capacity vary greatly, depending on the solvent used, as shown in the tables below.

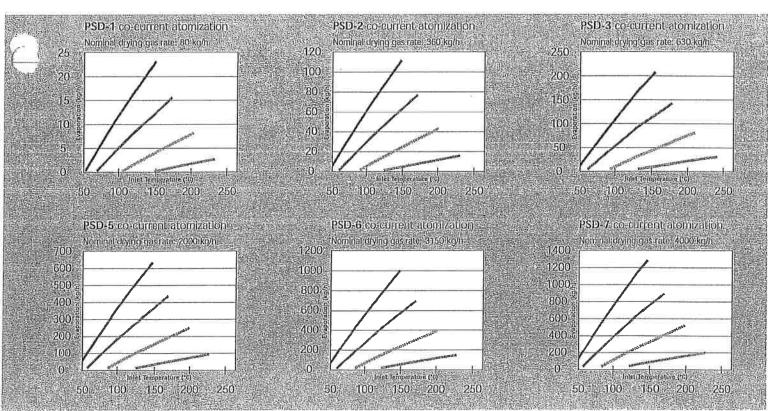




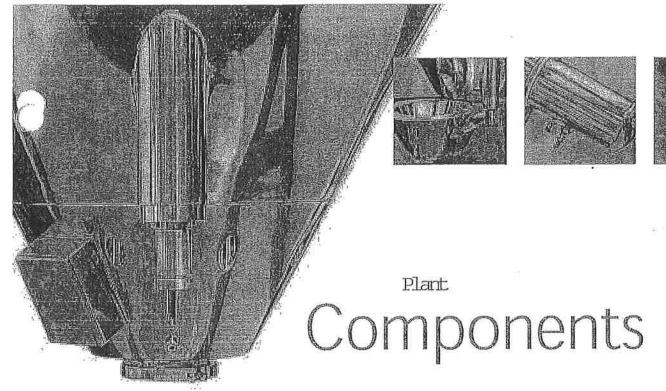


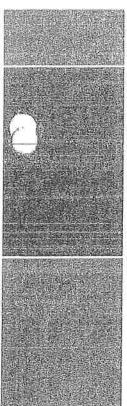


PSD-2 Spray dryer equipped with steam sterilization







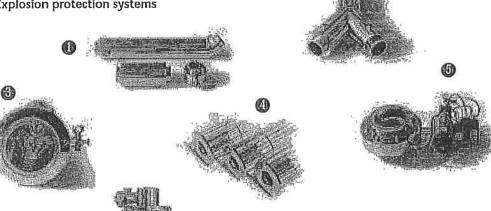


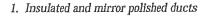
PharmaSD™ design options include:

- · Equipment for closed-cycle operation
- · Facilities for hot gas sanitization
- Special sanitary duct connections
- · Special construction materials
- · HEPA filters for gas streams
- Special process gas disperser design
- · Swirl cone for chamber access
- · CIP equipment
- · Mirror polished surface
- · Explosion protection systems

Single-unit manufacturing combined with the sue of standard modules has replaced serial plant production withing the pharmaceutical industry, enabling truly customized solutions based on proven systems.

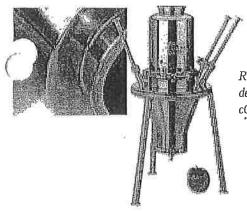
Each module, indeed each system component, must meet the strictest requirements and regulatory standards around the world.





- 2. V-duct with ports for CIP nozzles
- 3. Removable CIP nozzle mounted in duct
- 4. Bag filter cages
- 5. Actuated damper with inflatable sealing
- 6. Insulated cyclone: Ø 140mm





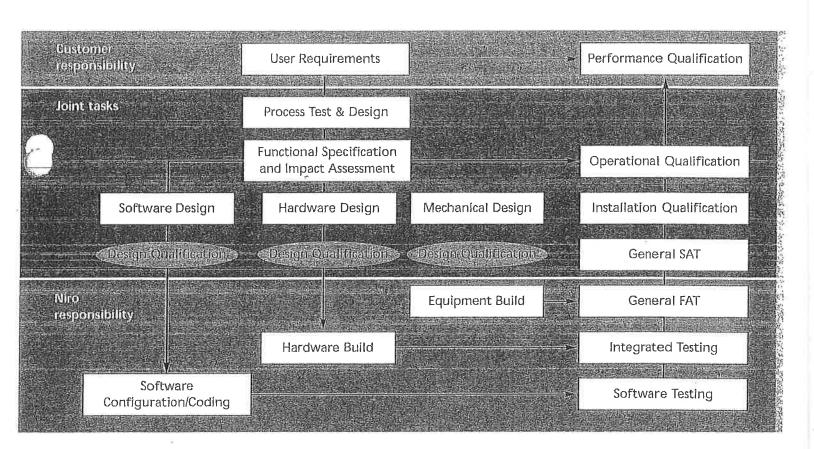
Rotary atomizer F1.5 X designed to meet cGMP requirements

The Complete

#### Partnership

#### Working with You...

Entering a partnership with Niro means entering a partnership that does not end until you are completely satisfied. From the moment you have specified your user requirements and until the plant has been put into service and has been qualified, our trained staff stays with you at every step of the process, working in close co-operation with your own staff creating the components and systems that will result in a finished plant.



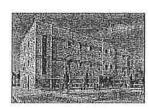
#### **Every Step of the Way**

Based on years of experience, equipment qualification will be carried out according to an agreed plan using documents prepared by Niro. Our engineers will contribute to a successful qualification of the equipment in close co-operation with your validation staff.



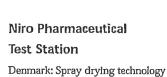
#### Niro Pharma Systems

REBONALIC BOCK ELLE SOLE LIE DES MICE MEO



Niro Pharmaceutical Technology Centre

USA: Coating and drying technology



Niro Pharma Systems is world leader in providing advanced processing solutions for solid dosage forms to the pharmaceutical industry. Based on a dedication to research and durable quality, Niro Pharma Systems offers a wide range of solutions, from individual pieces of equipment to complete integrated plants, by uniting the state-of-the-art technologies of Aeromatic, Buck, Collette, Courtoy, Fielder, Nica and Niro.



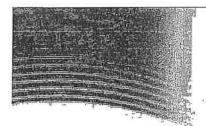
NPS Technology Center
Switzerland: Solid dosage technology



Niro A/S Denmark



Niro Inc. 9165 Rumsey Road Columbia, MD 21045 Tel: +1 410 997 8700 • Fax: +1 410 997 5021 E-mail: info@.nlro.com



WWW.NIROINC.COM



Niro Pharma Systems

Process Engineering

A company of mg technologies group



Niro Inc.

#### SPECIFICATION FOR MOBILE MINOR SPRAY DRYER

1. <u>CO-CURRENT TWO-FLUID NOZZLE ATOMIZER</u>, externally mixing, two-fluid nozzle to be mounted in the roof of the drying chamber. The nozzle lance, body, orifice, and air cap are fabricated in stainless steel, type AISI 316. The system is supplied with a 0.5mm orifice, fittings for the air hose connection, air pressure regulator, and air flow meter.

Compressed air must be supplied by the customer at 10 - 50 psig and a maximum of 8 scfm.

- 2. DRYING CHAMBER with an inside diameter of 0.8 meters and is insulated with approximately 40 mm of Rockwool covered with a stainless steel outer shell. The chamber is provided with an interior light, observation pane for inspection during operation, and one rapping stud. The rapping stud is very useful in applications where sticky materials may attempt to build up in the chamber. The interior is made of stainless steel, type AISI 316. The exterior is stainless steel, type AISI 304. The roof of the drying chamber is made of stainless steel, type AISI 316, inside, and stainless steel, type AISI 304, outside. The entire roof can be lifted, using a special pneumatic lifting device and also tilts for ease of cleaning.
- 3. <u>AIR DISPERSER</u> made of stainless steel, type AISI 304, is built into the roof and specially designed to produce the desired air flow pattern necessary for proper drying of the atomized droplets.
- 4. <u>AIR DUCTS</u> made of stainless steel, type AISI 316, are provided with quick-release threaded fasteners, to ensure easy dismantling for ease of cleaning.
- 5. <u>CYCLONE</u> made of stainless steel, type AISI 316, is designed for maximum collection efficiency and ease of cleaning. The product is collected in a one liter glass jar, threaded to the cyclone discharge.
- 6. <u>EXHAUST FAN</u> made of silumin and is driven by a direct coupled, three (3) phase squirrel cage motor, 0.5 kW. The fan is rated for an air flow of 80 kg/hr (40 cfm).
- 7. <u>AIR HEATER</u>, 10.0 kW, infinitely variable. Maximum inlet air temperature is approximately 350 °C.



- 8. <u>INSTRUMENT PANEL</u> includes inlet air temperature controller, outlet air temperature indicator, and a switch for starting the fan and obtaining the base load for the electric air heater. The control panel is mounted on a mobile stand with the exhaust fan.
- 9. <u>SUPPORTING STRUCTURE</u> made of stainless steel, type AISI 304, with rubber castors for unit mobility.
- 10. SPARE PARTS
  - one set of gaskets for cyclone and air ducts.
  - one powder collecting jar.
  - one filter for Inlet air heater.
- 11. TOOLS for air duct connections.

Electrical Requirements:

230/460 Volt - 3 Ph - 60 Hz

Shipping Volume:

4.0 cubic meters (135 ft)

Gross Weight:

550 kg

Net Weight:

300 kg



Form AQM-5 Page 1 of 8

## **Emissions Information Application**

If you are using this form electronically, press F1 at any time for help

Process Information	Number of Individual Pieces of Process Equipment in Process: 1 - GMP Spray Dryer	Number of Individual Control Devices in Process: 1 - Carbon Beds
	₩:	2.

		Emissions In	Emissions Information for First Emission Point/Stack	mission Point/Stack		
3.	Emission Point Name: GMP	GMP Spray Dryer				
4.	Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:	rocess Equipment	and Control Devices Vent	ing Through Emission Poi	1	GMP Spray Dryer
5.	Pollutant Emissions					
If mor	If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.	is Emission Point/Sta	ck, attach additional copies of	this page as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 5.10 through 5.18)	CAS Number (Not required for 5.1 through 5.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
5.1.	Particulate Matter (PM)		0 lbs/hour	lbs/hour	tons/year	tons/year
5.2.	PM <sub>10</sub>	I	0 lbs/hour	lbs/hour	tons/year	tons/year
5.3.	PM <sub>2.5</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.4.	Sulfur Oxides (SO <sub>X</sub> )		0 lbs/hour	lbs/hour	tons/year	tons/year
5.5.	Nitrogen Oxides (NO <sub>X</sub> )		0 lbs/hour	lbs/hour	tons/year	tons/year
5.6.	Carbon Monoxide (CO)		0 lbs/hour	lbs/hour	tons/year	tons/year
5.7.	Total Volatile Organic Compounds (VOCs)		0.86 lbs/hour	0.09 lbs/hour	1.26 tons/year	0.127 tons/year
5.8	Total Hazardous Air Pollutants (HAPs)		1.47 lbs/hour	0.15 lbs/hour	2.14 tons/year	0.215 tons/year



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Ш	Emissions In	ons Information for First Emission Point/Stack	ission Point/Stack		
5.9. CO <sub>2</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.10. CO <sub>2e</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.11.		lbs/hour	lbs/hour	tons/year	tons/year
5.12.		lbs/hour	lbs/hour	tons/year	tons/year
5.13.		lbs/hour	lbs/hour	tons/year	tons/year
5.14.		lbs/hour	lbs/hour	tons/year	tons/year
5.15.		lbs/hour	lbs/hour	tons/year	tons/year
6. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	ion Necessary to	Understanding the Emissic	on Rates Provided Above:		
Attach the Basis of Determination or Calculations for each Emission Rate provided above.	tions for each Emis	ssion Rate provided above.			

							tons/year	/vear
						Requested Permitted Annual Emissions	tons	tons/vear
	<b>4</b> 1		nt/Stack:			Annual Potential to Emit (PTE)	tons/year	tons/year
	Emission Point/Stac		ing Through Emission Poi		his page as needed.	Maximum Controlled Emission Rate at Design Capacity	lbs/hour	lbs/hour
	ons Information for Second Emission Point/Stack		and Control Devices Vent	30	k, attach additional copies of	Maximum Uncontrolled Emission Rate at Design Capacity	lbs/hour	lbs/hour
The second secon	Emissions Info		rocess Equipment		s Emission Point/Stac	CAS Number (Not required for 9.1 through 9.10)		
	П	Emission Point Name:	Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:	Pollutant Emissions	If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.	Pollutant Name (Specify VOCs and HAPs Individually in 9.10 through 9.18)	Particulate Matter (PM)	PM <sub>10</sub>
		7.	ထ်	9.	If more		9.1.	9.2.



Form AQM-5 Page 3 of 8

	Em	Emissions Inform	nation for Second E	s Information for Second Emission Point/Stack	J.	
9.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
9.5.	Nitrogen Oxides (NO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
9.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
9.7.	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
9.8	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
9.9.	CO <sub>2</sub>		lbs/hour	lbs/hour	tons/year	tons/year
9.10.	CO <sub>2e</sub>		lbs/hour	lbs/hour	tons/year	tons/year
9.11.			lbs/hour	lbs/hour	tons/year	tons/year
9.12.			lbs/hour	lbs/hour	tons/year	tons/year
9.13.			lbs/hour	lbs/hour	tons/year	tons/year
9.14.			lbs/hour	lbs/hour	tons/year	tons/year
9.15.			lbs/hour	lbs/hour	tons/year	tons/year
10.	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	n Necessary to Ur	nderstanding the Emissic	on Rates Provided Above:		
Affach	Attach the Basis of Determination or Calculations for each Emission Rate provided above.	ons for each Emission	n Rate provided above.			

Point/Stack	
<b>Emission F</b>	
for Third	
Information for	
<b>Emissions</b> I	

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Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack: 12.

## 13. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.



Form AQM-5 Page 4 of 8

		Emissions Inf	Emissions Information for Third Emission Point/Stack	mission Point/Stack		
	Pollutant Name (Specify VOCs and HAPs Individually in 13.10 through 13.18)	CAS Number (Not required for 13.1 through 13.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
13.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
13.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
13.5.	Nitrogen Oxides (NO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
13.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
13.7.	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
13.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
13.9.	CO <sub>2</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.10.	CO <sub>2e</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.11.			lbs/hour	lbs/hour	tons/year	tons/year
13.12.			lbs/hour	lbs/hour	tons/year	tons/year
13.13.			lbs/hour	lbs/hour	tons/year	tons/year
13.14.			lbs/hour	lbs/hour	tons/year	tons/year
13.15			lbs/hour	lbs/hour	tons/year	tons/year
14.	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	ation Necessary to	Understanding the Emissi	on Rates Provided Above		
Attach (	Attach the Basis of Determination or Calculations for	lations for each Emis	each Emission Rate provided above.			



Form AQM-5 Page 5 of 8

Emission Point Name:	Emissions Informatio	on for Fourth E	ons Information for Fourth Emission Point/Stack		
cess	Equipment and Cor	ntrol Devices Ventir	Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:	nt/Stack:	
					30
-missi	If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.	additional copies of the	is page as needed.		
Not red 7.1 thr	CAS Number (Not required for 17.1 through 17.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
	_	lbs/hour	lbs/hour	tons/year	tons/year
		lbs/hour	lbs/hour	tons/year	tons/year
		lbe/bour	lbs/hour	fons/vear	tons/vear



Form AQM-5 Page 6 of 8

## **Emissions Information for Fourth Emission Point/Stack**

Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above: 18.

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

If there are more than four Emission Points/Stacks, attach additional copies of this form as needed.

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		Requested Permitted Annual Emissions	tons/year	tons/year	tons/year	tons/year	tons/year	tons/year	0.127 tons/year	0.215 tons/year	tons/year	tons/year	tons/year
		Annual Potential to Emit (PTE)	tons/year	tons/year	tons/year	tons/year	tons/year	tons/year	1.26 tons/year	2.14 tons/year	tons/year	tons/year	tons/year
	ıs needed.	Maximum Controlled Emission Rate at Design Capacity	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	0.09 lbs/hour	0.15 lbs/hour	lbs/hour	lbs/hour	lbs/hour
	additional copies of this page a	Maximum Uncontrolled Emission Rate at Design Capacity	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	0.86 lbs/hour	1.47 lbs/hour	lbs/hour	lbs/hour	lbs/hour
	ι this Process, attach a	CAS Number (Not required for 19.1 through 19.10)											
Pollutant Emissions	If more than 15 pollutants are emitted from this Process, attach additional copies of this page as needed.	Pollutant Name (Specify VOCs and HAPs Individually in 19.10 through 19.18)	Particulate Matter (PM)	PM <sub>10</sub>	PM <sub>2.5</sub>	Sulfur Oxides (SO <sub>X</sub> )	Nitrogen Oxides (NO <sub>X</sub> )	Carbon Monoxide (CO)	Total Volatile Organic Compounds (VOCs)	Total Hazardous Air Pollutants (HAPs)	200	CO <sub>2e</sub>	
19. F	If more ti		19.1.	19.2.	19.3.	19.4.	19.5.	19.6.	19.7.	19.8.	19.9.	19.10.	19.12.



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	Ó	Overall Process Emissions	sions		
19.13.		lbs/hour	lbs/hour	tons/year	tons/year
19.14.		lbs/hour	lbs/hour	tons/year	tons/year
19.15,		lbs/hour	lbs/hour	tons/year	tons/year
20. Provide Any Additional Information Necessary to Understanding the Emission Rafes Provided Above:	Necessary to Ur	nderstanding the Emissio	n Rates Provided Above:		
Attach the Basis of Determination or Calculations for each Emission Rate provided above.	ns for each Emission	n Rate provided above.			
	Minor Ne	Minor New Source Review Information	nformation	¥?	
21. Does the Process Have the Potential to Emit More Than Five Tons Per Year of Any Pollutant?	tial to Emit More	Than Five Tons Per Year		☐ YES 図 NO	
22. Is the Source New or Existing? See Question 11 of AQM-1	NEW ☐ EXISTING	STING			
If the Process has the Potential to Emit more than five tons per year of any pollutant, and is a New Source, a Control Technology Analysis pursuant to Regulation No. 1125 Section 4 must be conducted and attached to this application.	an five tons per year I to this application.	r of any pollutant, and is a Ne	ew Source, a Control Technolo	gy Analysis pursuant to F	Regulation No.
65					
	Major Ne	Major New Source Review Information	nformation		
23. Does the Process Have the Potential to Emit More Than the Significance Level for Any Pollutant? (Check All That Apply)	tial to Emit More	Than the Significance Le	vel for Any Pollutant? (Ch	eck All That Apply)	
Greater Than 25 Tons Per Year of Particulate Matter (PM)  Greater Than 15 Tons Per Year of PM <sub>10</sub> Greater Than 10 Tons Per Year of PM <sub>2.5</sub> Greater Than 40 Tons Per Year of Sulfur Dioxide(SO <sub>2</sub> )  Greater Than 25 Tons Per Year of Nitrogen Oxides (NO <sub>x</sub> )  Greater Than 100 Tons Per Year of Nitrogen Oxides (NO <sub>x</sub> )  Greater Than 100 Tons Per Year of Carbon Monoxide (CC  Greater Than 25 Tons Per Year of Total Volatile Organic C  Greater Than 50 Tons Per Year of Total Volatile Organic C  Greater Than 50 Tons Per Year of Total Volatile Organic C	r of Particulate M r of PM <sub>10</sub> r of PM <sub>2.5</sub> r of Sulfur Dioxide r of Nitrogen Oxiar of Nitrogen Oxar of Carbon Morar of Total Volatile r of Total Volatile Year of Equivale	Than 25 Tons Per Year of Particulate Matter (PM)  Than 15 Tons Per Year of PM <sub>10</sub> Than 10 Tons Per Year of PM <sub>2.5</sub> Than 40 Tons Per Year of Sulfur Dioxide(SO <sub>2</sub> )  Than 40 Tons Per Year of Sulfur Dioxide(SO <sub>2</sub> )  Than 25 Tons Per Year of Nitrogen Oxides (NO <sub>x</sub> ) in New Castle and Kent County  Than 100 Tons Per Year of Nitrogen Oxides (NO <sub>x</sub> ) in Sussex County  Than 100 Tons Per Year of Carbon Monoxide (CO)  Than 25 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex C  Than 50 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex C  Than 75,000 Tons Per Year of Equivalent Carbon Dioxide (CO <sub>2e</sub> )	Than 25 Tons Per Year of Particulate Matter (PM)  Than 15 Tons Per Year of PM <sub>10</sub> Than 10 Tons Per Year of PM <sub>2.5</sub> Than 40 Tons Per Year of Sulfur Dioxide(SO <sub>2</sub> )  Than 40 Tons Per Year of Sulfur Dioxides (NO <sub>x</sub> ) in New Castle and Kent County  Than 25 Tons Per Year of Nitrogen Oxides (NO <sub>x</sub> ) in Sussex County  Than 100 Tons Per Year of Nitrogen Oxides (CO)  Than 100 Tons Per Year of Total Volatile Organic Compounds (VOCs) in New Castle and Kent County  Than 50 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex County  Than 75,000 Tons Per Year of Equivalent Carbon Dioxide (CO <sub>2e</sub> )	ent County	



Form AQM-5 Page 8 of 8 If the Process has the Potential to Emit greater than any of the amounts listed above 7 DE Admin. Code 1125 Sections 2 and/or 3 apply. Contact the Department at (302) 323-4542 or (302) 739-9402 for additional information

24. Is There Any Additional Information Pertinent to this Application?  If YES, complete the rest of Question 24.  24.1. Describe:
--

rate (7)		А	kg/hr	<u> </u>	· -		i -		wed 5/17/20							
Time (2)			hr/batch								-					
	. (3)									-	-					-
vent Use			kg/batch/day							-	-					-
erating D	avs/vr.,	292	days/yr							-	-					-
unnt Com	us Delad	11680	lea/se								-	_				-
vent Spra				CAL former		l										
	Max. venting gas rate (5)		. 505	EN (round	led to the next	whole value)				-				-		-
	Operating Hours Total Gas Vented(6)	2,920		75N						-	-	Control	ne with 1000	of One Solver	.+	_
	otal Gas vented.	35,040	kg/yr NITRO	JEN Vente							-	Emissic	JIIS WILLI TOOM	or one solver		-
	Typical Solvent Mix <sup>(9)</sup>	%	kg/γr Solvent (pre condenser)	Solvent Factor <sup>(7)</sup> (kg/kg)	Calculated kg/yr exhausted <sup>(8)</sup>	Maximum kg/yr exhausted (post condenser)	Maximum Ib/hr exhausted (post condenser)*	Maximum tons/year exhausted (post condenser)	Annual Emissions as a 12 month rolling period (TPY)		% Solvent	kg/yr Solvent (pre condenser)	Calculated kg/yr exhausted	Max kg/yr exhausted (post condenser)	Max lb/hr exhausted (post condenser)	Max lb, exhausi (post car beds)
-	Ethanol	17.0%	1,985.6	0.04	224.4	224.4	0.169	0.247	0.025		100%	11680	1,320,0	1.320.0	0.995	0.
	Methanol	35.0%	4,088,0	0.06	778.7	778,7	0.587	0.857	0.086		100%	11680	2,224.8	2,224.8	1.676	0.
	IPA	1.0%	116.8	0.03	11.0	11.0	0.008	0.012	0.001		100%	11680	1,104.6	1,104.6	0.832	0.
	Ethy Acetate	1,0%	116.8	0.14	50.0	50.0	0.038	0.055	0.006		100%	11680	5,004.5	5,004.5	3.771	0
	Methylene Chloride	10.0%	1,168.0	0.41	1,427.2	1,168.0	0.880	1,285	0.128		100%	11680	14,271.9	11,680.0	8,800	0
	THE	1.0%	116.8	0,22	77.3	77.3	0.058	0.085	0.009		100%	11680	7,733.8	7,733.8	5,827	0
	Acetone	35.0%	4,088.0	0.28	3,375.3	3,375.3	2.543	3.713	0.371		100%	11680	9,643.8	9,643.8	7.266	0
		65%	7,592.0	7.00	2,568.7	2,309.5	1.740	2.540	0.126	VOCs						
_			7,000.0	Later		- April	*1 kg = 2.2 lb			HAPs						
1	IOTES;															
	1) Based on equipment d	esign, the	max run rate	cannot ex	eed 4 kg/hr, t	pically it is run a	at 2 kg/hr to pro	duce quality r	naterial							
	2) The equipment runs in															
	nd assembly will take at															
	3) This is total maximum															
	4) Approximately 20% of															
	pray dried material need:								) i				U.		1	
	norphology. The max run															
	5) MAXIMUM GAS VENTI															
- '	- The vent rate of each F		r is up to 9.5 k	g/hr atomi:	zing gas (nomli	nally 6.5 kg/hr),										
	1.25 kg /hr bag house p															
	( it would modulate in c															
	Thus, maximum vent ra	te after th	e condenser t	olal max 1	1.75 kg/hr (rou	nded to 12 abov	e).									
	- Note: this is the require															
	Solvent vapor in the ve															
(	6) Ignores purging syster	n gas inve	ntory remaini	ng at end o	of batch, which	is negligibly sm	all relative to so	lvent in the								
(	7) Solvent Factors:															
	Solvent	MW	Max Cond Temp, C	(mmHg)	val % in N2 @	Solvent Factor (kg solv/ kg NZ vented)										
	Ethanol	45.10	5	17	2.24	0.038				_	-	-				-
	Methanol	32.00	5	40 89	5.26 11,71	0.063					-					-
_	Acetone	58.10	5	11	11.71	0,275					_					
	IPA Ethy Acetate	60,10 88.10	5	33	4.34	0,032										
	Methylene Chloride	84.90	-10	90	11.84	0.407										
	THF	72.10	5	60	7.89	0.221										
-	Condenser temperatures															
	meet desired process an				of the plo											
					anic Compoun	ds un to										
	Vanor Proceure Data Data			TI CO DI DIE	with chargedan	may alp to										
	Vapor Pressure Data Ref:				un to 1 Atm											
	Vapor Pressure Data Ref: 1 ATM, Table 3-8, Vapor Perry's Handbook, 5th ec	Pressures			up to 1 Atm											

		5												
Run Time <sup>(2)</sup>	8.0	8.0 hr/batch												
Solvent Used (3)	16	16 kg/batch/day												
Operating Days/yr <sup>(4)</sup>	182.5	182.5 days/yr			6									
Columb Corner Daired	and and a	land from												
15) -1	3	NEVY I												
Operation House	-	LE NEVER MILLIOUEN VIOLITIES LE NEXT WILDIE VAILE	ווסחווחפת וא	י נוופ ויפאר אוזס	le value)									
Total Gas Vented <sup>(6)</sup>	17,520	17,520 kg/yr NITROGEN vented	vented											
(6)		kg/yr Solvent (pre	Solvent Factor <sup>(7)</sup>	Calculated kg/yr	Expected kg/yr exhausted (post	Expected lb/hr exhausted (post	ą		kg/yr Solvent (pre	Calculated kg/yr	Expected kg/yr exhausted (post	Expected Ib/hr exhausted (post	Expected Emissions (lb/hr) after	
Ethanol	17.0%	congenser)	0.04 0.04	112.2	condenser)	Condenser]*	condenser)	100%	condenser)	exhausted 660.0	condenser)	condenser]	carbon beds	
Methanol	35.0%	1,022.0	90'0	389.3	389.3	0.587	0.428	100%	2920	1,112.4	1.112.4	1.676	0.168	
IPA	1.0%	29.2	0.03	5.5	5.5	0.008	0.006	100%	2920	552.3	552.3	0.832	0.083	
Ethyl Acetate	1.0%	29.2	0.14	25.0	25.0	0.038	0.028	100%	2920	2.502.3	2,502.3	3.771	0.377	
Methylene Chloride	100.0%	2,920.0	0.41	7,135.9	2,920.0	4.400	3.212	100%	2920	7,135.9	2,920.0	4.400	0.440	
岸	1.0%	29.2	0.22	38.7	29.2	0.044	0.032	100%	2920	3,866.9	2,920.0	4,400	0.440	
Acetone	35.0%	1,022.0	0.28	1,687.7	1,022.0	1.540	1.124	100%	2920	4,821.9	2,920.0	4.400	0.440	
	155%	4,526.0		7,706.7	3,481.3	5.246	3.829							
NOTES						*1 kg = 2.2 lb								
(1) Based on equipment design, the max run rate cannot	t design.	he max run rate		od 4 kg/hr tun	irelly it is run a	+ 3 balbren	exceed 4 kether trained by it is an a 2 kether to an addition and a feet of the feet of th	Iciao						
(2) The equipment is runs in batches, one batch per day. assembly will take at least 14 hours. The actual run time	ins in batc ast 14 hou	hes, one batch pe irs. The actual rur		In between batches the time is typically less than 8 hours.	the time for d 8 hours.	isassembly, clea	In between batches the time for disassembly, cleaning, drying and is typically less than 8 hours.							
(3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the solids	m Kg = 50	ilvent + solids. To	be consen	ative, consider	it all solvent a	nd do not adjus	st out the solids							
(4) Less than half of the time the spray dryer will be running. 365 days*0,5=182.5 days	time the	spray dryer will b	e running.	165 days*0.5=1	.82.5 days									
(5) MAXIMUM GAS VENTING RATE:	VTING RAT	نن												
- ine vent rate of each PSD1 dryer is up to 9.5 kg/hr atomizing gas (nominally 6.5 kg/hr)	h PSD1 a	ryer is up to 9.5 k	g/hr atomiz	ng gas (nomir	ally 6.5 kg/hr),									
1.25 kg /hr bag house pulse cleaning, and 1 kg/hr system pressure control	se pulse o	leaning, and 1 kg	J/hr system	pressure cont	lo									
This maying unitate after the condenses total may 44.75 balls for maded to 42 above.	it role offer	r the candenser	Pillallina Pilallina	75 beiler feet	order of any hope	i en								
- Note; this is the required venting rate for non-condensable N2 to maintain pressure.	lired vent	ng rate for non-or	ondensable	N2 to maintair	pressure.									
Solvent vapor in the vented stream is in addition to the 11.75 kg/Hr.	s vented s	ream Is in additio	n to the 11.	75 kg/Hr.										
<ul> <li>Ignores: purging system gas inventory remaining at end of batth, which is negligibly small relative to solvent in the vent</li> <li>(7) Solvent Factors:</li> </ul>	tem gas ir	iventory remainin	g at end of	batch, which is	negligibly sma	Il relative to so	ivent in the vent							
		May Cond	Vapor Pressure @ max cond	CM ri % lov	Solvent Factor									
Solvent	MM	Temp, C	(mmHg)	@ 1 ATM	ke N2 vented)									
Ethanol	46.10	N	17	2.24	0.038									
Methanol	32.00	w	40	5,26	0.063									
Acetone	58.10	5	68	11.71	0.275									
IPA	60.10	ľ	11	1.45	0.032									
Ethyl Acetate	-	5	33	4.34	0.143									
Methylene Chloride	84.90	-10	90	11.84	0.407									
THF	72.10	5	90	7.89	0.221									
- Condenser temperatures indicated are the maximum required by the process to	res indica	ted are the maxin	num require	ed by the proce	ess to									
meet desired process and product specifications.	and prod	uct specifications.												
<ul> <li>Vapor Pressure Data Ref: Table 3-8, Vapor Pressures of</li> </ul>	ef: Table	3-8, Vapor Pressu	res of Orga	Organic Compounds, up to	s, up to									
1 ATM, Table 3-8, Vapor Pressures of Organic Compounds, up to 1 Atm.	or Pressu	res of Organic Co	mpounds, u	p to 1 Atm.										
Perry's Handbook, 5th ed.	Ted.													

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GMP Spray Dryer (PSD-1)	3D-1)		T.	Potential To Emit	1	Expecte	Expected Emission	Perm	Permit Limits
<u>Pollutant</u>	VOC?	HAP?	Maximum Uncontrolled Emission Rate Ib/hr <sup>(2)</sup>	Maximum Controlled Emission Rate Ib/hr(1),(2)	Annual Potential To Emit (PTE) (tons/yr) <sup>(1),(2)</sup>	Expected Annual Uncontrolled Emissions (tons/vr)	Expected Annual Controlled Emissions (tons/yr) <sup>(1)</sup>	Emissions (lb/hr) after carbon beds	Annual Emissions as a 12 month rolling period (TPY)
Ethanol	Yes	No	0.169	0.017	0.247	0.123	0.012	0.099	0.025
Methanol	Yes	Yes	0.587	0.059	0.857	0.428	0.043	0.168	
IPA	Yes	No	0.008	0.001	0.012	0.006	0.001	0.083	0.001
Ethyl Acetate	Yes	No	0.038	0.004	0.055	0.028	0.003	0.377	0:006
Methylene Chloride	No	Yes	0.880	0.088	1.285	3.212	0.321	0.880	0.128
Tetrahydrofuran (THE)	Yes	No	0.058	9000	0.085	0.032	0.003	0.583	0.009
Acetone	No	No	2.543	0.254	3.713	1.124	0.112	0.727	0.371
VOC		12.0 E	98.0	60.0	1.26	0.62	90.0	NA	0.126
HAP			1.47	0.15	2.14	3.64	0.36	NA	0.214
Notes:									
(1) The controlled emissions assume a carbon adsorption control efficiency of 90%. There are two carbon canisters operating in series, so the actual control efficiency will be greater than 90%.	assume a	carbon a greater tl	dsorption control han 90%.	efficiency of 90%	%. There are two	carbon canisters	operating in series,		
(2) Acetone, as defined by the US EPA, is neither a VOC nor a HAP, and the totals are not included in the VOC or HAP totals.	e US EPA	, is neith	er a VOC nor a E	IAP, and the total	s are not include	d in the VOC or H	LAP totals.		

## SD-Micro Spray Dryer

Form AQM-3.1 Page 1 of 6

## **Generic Process Equipment Application**

If you are using this form electronically, press F1 at any time for help

-									
		<u>General Infor</u>	mation						
1.	Facility Name: Hercul	es / Ashland Research Cente	er						
2.	Equipment ID Number	SD Micro Spray Dryer							
3.			Bench scale spray dryer for d through two carbon adsork						
4.	Manufacturer: Niro/G	<b>EA</b>							
5.	Model:								
6.	Serial Number: 90020	2							
		Raw Material Int	<u>formation</u>						
7.	Raw Materials Used in	Process	V SALES OF THE SAL						
If ther	e are more than four Raw Ma	aterials used, attach additional copi	ies of this page as needed.						
	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?					
7.1.	Active pharmaceuticals and excipients	N/A	Varies	☐ YES ☐ NO					
7.2.	Ethanol	64-17-5	745 kg/yr average	☐ YES ☑ NO					
7.3.	Methanol	67-56-1	1533 kg/yr average	☐ YES ☐ NO					
7.4.	Acetone	67-64-1	1533 kg/yr average	☐ YES ☐ NO					
		nade to support the data in the table et (MSDS) for <u>each</u> Raw Material use							
		Products Produced	l Information						
8.	Products Produced								
If ther	e are more than four Product	ts Produced, attach additional copie	es of this page as needed.						
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?					
8.1.	R&D pharmaceuticals	N/A	Various	☐ YES ☐ NO					
8.2.				☐ YES ☐ NO					
8.3.				☐ YES ☐ NO					
8.4				☐ YES ☐ NO					

Form AQM-3.1 Page 1a of 6

## **Generic Process Equipment Application**

If you are using this form electronically, press F1 at any time for help

	General Information
1.	Facility Name: Hercules / Ashland Research Center
2.	Equipment ID Number: SD Micro Spray Dryer
3.	Provide a brief description of Equipment or Process: <b>Bench scale spray dryer for pharmaceutical</b> research. The uncontrolled emissions are vented through two carbon adsorber beds in series.
4.	Manufacturer: Niro/GEA
5.	Model:
6.	Serial Number: 900202

	Raw Material	<u>Information</u>	
7. Raw Materials Used in	n Process		
If there are more than four Raw M	aterials used, attach additio	nal copies of this page as needed.	
Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1. Isopropanol	67-63-0	44 kg/yr average	YES X NO
7.2. Ethyl Acetate	141-78-6	44 kg/yr average	YES X NO
7.3. Methylene Chloride	75-09-2	438 kg/yr average	YES X NO
7.4. Tetrahydrofuran	109-99-9	44 kg/yr average	YES X NO

		Products Produ	uced Information	
8.	Products Produced			
If the	re are more than four Produc	cts Produced, attach additional	copies of this page as needed.	
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1,				☐YES ☐NO
8.2.				☐YES ☐NO



Form AQM-3.1 Page 2 of 6

		Products Products	oduced Information		
	h a copy of a <u>ll</u> calculations m h a Material Safety Data Shee				
		Byproducts G	enerated Information		
9.	Byproducts Generated				
If ther	re are more than four Byprod	lucts Generated, attach ac	dditional copies of this page as needed	d.	
	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?	
9.1.				☑ YES ☐ NO	
9.2.				☐ YES ☐ NO	
9.3.				☐ YES ☐ NO	
9.4.				☐ YES ☐ NO	
	l h a copy of a <u>ll</u> calculations m h a Material Safety Data Shee				
Au	I a material outry	it (mode) to:	Aude Ocherateur.		
		Genera	al Information		
10.	Manufacturer's Rated 0 cannot exceed 1.5 kg/		Throughput of Equipment or Pro	cess: Maximum run rate	
11.	Describe Important Ma Process: See attached		ons and/or Operating Parameters	for Equipment or	
Attack	h the Manufacturer's Specific	cation Sheet(s) for the equ	uipment or process.		
Control Device Information					
12. Is an Air Pollution Control Device Used? ☐ YES ☐ NO					
If an .	If an Air Pollution Control Device is used, complete the rest of Question 12. If not, proceed to Question 13.				
	Is Knockout Used?		☐ YES 🖾 NO		
If YES	s, complete Form AQM-4.11 a	nd attach it to this applica			
	Is a Settling Chamber U		☐ YES 🖾 NO		
If YES	s, complete Form AQM-4.10 a	nd attach it to this applica			
	Is an Inertial or Cyclone		☐ YES ⊠ NO		
KVEC	complete Form AQM-4.5 ap				
	Is a Fabric Collector or	nd attach it to this applicat	tion.		

☐ YES ⊠ NO

12.5. Is a Venturi Scrubber Used?



Form AQM-3.1 Page 3 of 6

Control Device Information
If YES, complete Form AQM-4.8 and attach it to this application.
12.6. Is an Electrostatic Precipitator Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.7 and attach it to this application.
12.7. Is Adsorption Equipment Used?  ☐ YES ☐ NO
If YES, complete Form AQM-4.2 and attach it to this application.
12.8. Is a Scrubber Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.4 and attach it to this application.
12.9. Is a Thermal Oxidizer or Afterburner Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.1 and attach it to this application.
12.10. Is a Flare Used? ☐ YES ☐ NO
If YES, complete Form AQM-4.3 and attach it to this application.
12.11. Is Any Other Control Device Used? ☐ YES ☐ NO
If YES, attach a copy of the control device Manufacturer's Specification Sheet(s).
If any other control device is used, complete the rest of Question 12. If not, proceed to Question 13.
12.12. Describe Control Device:
12.13. Pollutants Controlled: ☐ VOCs ☐ HAPs ☐ PM ☐ PM <sub>10</sub> ☐ PM <sub>2.5</sub> ☐ NO <sub>X</sub> ☐ SO <sub>X</sub> ☐ Metals ☐ Other (Specify):
12.14. Control Device Manufacturer:
12.15. Control Device Model:
12.16. Control Device Serial Number:
12.17. Control Device Design Capacity:
12.18. Control Device Removal or Destruction Efficiency:
Stack Information
13. How Does the Process Equipment Vent: (check all that apply) ☐ Directly to the Atmosphere ☑ Through a Control Device Covered by Forms AQM-4.1 through 4.12 ☐ Through Another Control Device Described on This Form  If any of the process equipment vents directly to the atmosphere or through another control device described
on this form, proceed to Question 14. If the process equipment vents through a control device, provide the stack parameters on the control device form and proceed to Question 18.
14. Number of Air Contaminant Emission Points: 1
If there are more than three Emission Points, attach additional copies of this page as needed.
For the first Emission Point
15. Emission Point Name: SD Micro Spray Dryer
15.1. Stack Height Above Grade: 10 feet



Form AQM-3.1 Page 4 of 6

Stack Information
15.2. Stack Exit Diameter: 0.333 feet (Provide Stack Dimensions If Rectangular Stack)
15.3. Is a Stack Cap Present? ☐ YES ☒ NO
15.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☑ Downward-Venting (check all that apply) ☐ Other (Specify):
15.5. Stack Exit Gas Temperature: <b>20 °C</b>
15.6. Stack Exit Gas Flow Rate: 13 ACFM
15.7. Distance to Nearest Property Line: <b>362 feet</b>
15.8. Describe Nearest Obstruction: Building 8162
15.9. Height of Nearest Obstruction: 32 feet
15.10. Distance to Nearest Obstruction: 0 feet
15.11. Are Stack Sampling Ports Provided? ☐ YES ☒ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.
16. Emission Point Name:
16.1. Stack Height Above Grade: feet
16.2. Stack Exit Diameter: feet (Provide Stack Dimensions If Rectangular Stack)
16.3. Is a Stack Cap Present?
16.4. Stack Configuration:  Vertical  Horizontal Downward-Venting (check all that apply) Other (Specify):
16.5. Stack Exit Gas Temperature: °F
16.6. Stack Exit Gas Flow Rate: ACFM
16.7. Distance to Nearest Property Line: feet
16.8. Describe Nearest Obstruction:
16.9. Height of Nearest Obstruction: feet
16.10. Distance to Nearest Obstruction: feet
16.11. Are Stack Sampling Ports Provided?
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.
17. Emission Point Name:
17.1. Stack Height Above Grade: feet
17.2. Stack Exit Diameter: feet (Provide Stack Dimensions If Rectangular Stack)
17.3. Is a Stack Cap Present?
17.4. Stack Configuration: Vertical Horizontal Downward-Venting (check all that apply) Other (Specify):
17.5. Stack Exit Gas Temperature: °F
17.6. Stack Exit Gas Flow Rate: ACFM
17.7. Distance to Nearest Property Line: feet



Form AQM-3.1 Page 5 of 6

Stack Information	
17.8. Describe Nearest Obstruction:	
17.9. Height of Nearest Obstruction: feet	
17.10. Distance to Nearest Obstruction: feet	
17.11. Are Stack Sampling Ports Provided?	
	_
Monitoring Information	
18. Will Emissions Data be Recorded by a Continuous Emission Monitoring ☐ YES ☒ NO System?	
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.1. Pollutants Monitored: VOCs HAPs PM PM <sub>10</sub> PM <sub>2.5</sub> NO <sub>X</sub> SO <sub>X</sub> Metals Other (Specify):	
18.2. Describe the Continuous Emission Monitoring System:	
18.3. Manufacturer:	
18.4. Model:	
18.5. Serial Number:	
18.6. Will Multiple Emission Units Be Monitored at the Same Point?	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.7. Emission Units Monitored:	
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At ☐ YES ☐ NO Any Time?	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.9. Emission Units Emitting Simultaneously:	
Voluntary Emission Limitation Request Information	_
19. Are You Requesting Any <u>Voluntary Emission Limitations</u> to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, ☐ YES ☒ NO etc.?	
If YES, complete the rest of Question 19. If NO, proceed to Question 20.	
19.1. Describe Any Requested Emission Limitations:	
Valuations On carting Limitation Decrease Information	_
Voluntary Operating Limitation Request Information	
20. Are You Requesting Any <u>Voluntary Operating Limitations</u> to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, ☐ YES ☒ NO etc.?	

Form AQM-3.1 Page 6 of 6

	Voluntary Operating Limitation Request Information	
If YE	S, complete the rest of Question 20. If NO, proceed to Question 21.	
20.1.	Describe Any Requested Operating Limitations:	
	Additional Information	
21.	Additional Information  Is There Any Additional Information Pertinent to this Application? ☐ YES ☒ NO	

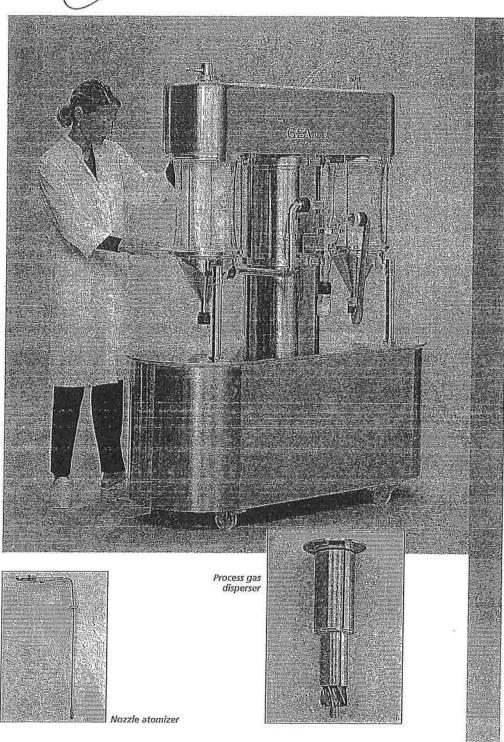


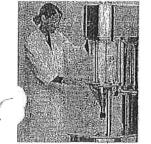
Niro

## SDMicro™ Spray Dryer



- Ideal for research and development
- Designed for spray drying of small volumes of high value pharmaceutical and chemical formulations
- Water or organic solvent based formulations can be spray dried by using compressed air or inert process gass
- Two-fluid nozzle atomization
- High efficiency cyclone and bag filter
- Easy to dismantle for cleaning and fast product switch





### SDMicro™ Spray Dryer

The new SDMicro<sup>TM</sup> Spray Dryer helps pharmaceutical or chemical companies to evaluate spray drying during the early stages of product development. It enables companies to identify the most appropriate isolation technique for the product to guarantee the most efficient manufacturing process.

The SDMicro™ is a fully functional spray drying plant in very small scale. Computational Fluid

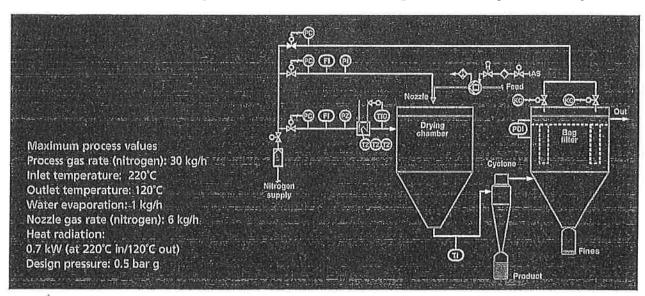
Dynamics have been used to design the smallest possible spray drying chamber that retained the same air flow pattern as a full scale production model. The resulting equipment can make test volumes of product at the smallest possible scale (100 - 200 ml).

The Intrinsically Safe operation makes the SDMicro<sup>TM</sup> suitable for use with Nitrogen for products dissolved in organic sol-

vents. Compressed air is used for drying of aqueous fluids.

The cyclone is used for the initial powder collection, and the bag filter collects fine particles passing through the cyclone. The cyclone may be by-passed completely for collecting very fine powders in the bag filter.

The SDMicro™ is easy to dismantle for simple cleaning and fast product switching.



### Configuration example

Item 1: Lower part

Item 2: Cyclone, stainless steel or glass, with powder recovery

Item 3: Drying Chamber including the two-fluid nozzle. Cylinder made of glass

Item 4: Middle section including the electrical heater, 2 kW, class EEx de IIC T1, T2, T3

Item 5: Exhaust gas bag filter. Cylinder made of glass. 4 bags of PTFE. Filter area: 0.3 m<sup>2</sup> Continuous 'pulse let' cleaning.

Item 6: Upper part

Item 7: Process gas disperser

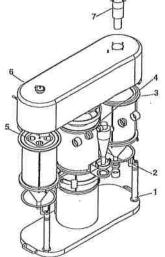
Control system with animated HMI LC display Glass type: Boro Silicate Stainless steel: AISI 316

### **Dimensions**

Assembled LxWxH:1200 x 600 x 1700 mm Weight (exclusive of control panel): 200 kg Control panel: 150 kg



Powder Technology Division





Form AQM-5 Page 1 of 8

## **Emissions Information Application**

If you are using this form electronically, press F1 at any time for help

Process Information	1. Number of Individual Pieces of Process Equipment in Process: 1 - SD Micro Spray Dryer	2. Number of Individual Control Devices in Process: 1 - Carbon Beds
---------------------	--	---

		Emissions In	<b>Emissions Information for First Emission Point/Stack</b>	mission Point/Stack		
.9	Emission Point Name: SD Micro Spr	icro Spray Dryer				
4.	Equipment ID Number for all Process		Equipment and Control Devices Venting Through Emission Point/Stack:	ing Through Emission Poi	1	SD Micro Spray Dryer
5.	Pollutant Emissions					
If more	If more than 15 pollutants are emitted at this Emissi	is Emission Point/Sta	on Point/Stack, attach additional copies of this page as needed.	this page as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 5.10 through 5.18)	CAS Number (Not required for 5.1 through 5.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
5.1.	Particulate Matter (PM)		0 lbs/hour	lbs/hour	tons/year	tons/year
5.2.	PM <sub>10</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.3.	PM <sub>2.5</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.4.	Sulfur Oxides (SO <sub>X</sub> )		0 lbs/hour	lbs/hour	tons/year	tons/year
5.5.	Nitrogen Oxides (NO <sub>x</sub> )		0 lbs/hour	lbs/hour	tons/year	tons/year
5.6.	Carbon Monoxide (CO)		0 lbs/hour	lbs/hour	tons/year	tons/year
5.7.	Total Volatile Organic Compounds (VOCs)		1.82 lbs/hour	0.18 lbs/hour	2.65 tons/year	0.265 tons/year
5.8.	Total Hazardous Air Pollutants (HAPs)		1.49 lbs/hour	0.15 lbs/hour	2.17 tons/year	0.217 tons/year



Form AQM-5 Page 2 of 8

	Emissions In	ons Information for First Emission Point/Stack	nission Point/Stack		
5.9. CO <sub>2</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.10. CO <sub>2e</sub>		0 lbs/hour	lbs/hour	tons/year	tons/year
5.11.		lbs/hour	lbs/hour	tons/year	tons/year
5.12.		lbs/hour	lbs/hour	tons/year	tons/year
5.13.		lbs/hour	lbs/hour	tons/year	tons/year
5.14.		lbs/hour	lbs/hour	tons/year	tons/year
5.15.		lbs/hour	lbs/hour	tons/year	tons/year
6. Provide An	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	Understanding the Emissic	on Rates Provided Above:		
Attach the Basis of L	Attach the Basis of Determination or Calculations for each Emission Rate provided above.	ssion Rate provided above.			

	ы	missions Info	Emissions Information for Second Emission Point/Stack	Emission Point/Stac	الح	
7.	Emission Point Name:					
œ.	Equipment ID Number for all Process		Equipment and Control Devices Venting Through Emission Point/Stack:	ing Through Emission Pol	nt/Stack:	
တ်	Pollutant Emissions					
If moi	If more than 15 pollutants are emitted at this Emissi	s Emission Point/Sta	on Point/Stack, attach additional copies of this page as needed.	this page as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 9.10 through 9.18)	CAS Number (Not required for 9.1 through 9.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual
9.1	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
9.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
9.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year



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26	Emissio	ons Information for Second Emission Point/Stack	Emission Point/Stac	쑀	
9.4.	Sulfur Oxides (SO <sub>X</sub> )	lbs/hour	lbs/hour	tons/year	tons/year
9.5.	Nitrogen Oxides (NO <sub>x</sub> )	lbs/hour	lbs/hour	tons/year	tons/year
9.6.	Carbon Monoxide (CO)	lbs/hour	lbs/hour	tons/year	tons/year
9.7.	Total Volatile Organic Compounds (VOCs)	lbs/hour	lbs/hour	tons/year	tons/year
9.8.	Total Hazardous Air Pollutants (HAPs)	lbs/hour	lbs/hour	tons/year	tons/year
9.9.	CO <sub>2</sub>	lbs/hour	lbs/hour	tons/year	tons/year
9.10.	CO <sub>2e</sub>	lbs/hour	lbs/hour	tons/year	tons/year
9.11		lbs/hour	lbs/hour	tons/year	tons/year
9.12.		lbs/hour	lbs/hour	tons/year	tons/year
9.13		lbs/hour	lbs/hour	tons/year	tons/year
9.14		lbs/hour	lbs/hour	tons/year	tons/year
9.15.		lbs/hour	lbs/hour	tons/year	tons/year
10.	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	cessary to Understanding the Emiss	sion Rates Provided Above		
Attach t	Attach the Basis of Determination or Calculations for	r each Emission Rate provided above.			

	Emissions Information for Third Emission Point/Stack
<del>+</del>	1. Emission Point Name:
12.	12. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:
13.	13. Pollutant Emissions
If mo	If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.



Form AQM-5 Page 4 of 8

		Emissions Inf	Emissions Information for Third Emission Point/Stack	mission Point/Stack		
	Pollutant Name (Specify VOCs and HAPs Individually in 13.10 through 13.18)	CAS Number (Not required for 13.1 through 13.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
13.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
13.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
13.5.	Nitrogen Oxides (NOx)		lbs/hour	lbs/hour	tons/year	tons/year
13.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
13.7	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
13.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
13.9.	CO <sub>2</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.10.	CO <sub>2e</sub>		lbs/hour	lbs/hour	tons/year	tons/year
13.11.			lbs/hour	lbs/hour	tons/year	tons/year
13.12.			lbs/hour	lbs/hour	tons/year	tons/year
13.13.			lbs/hour	lbs/hour	tons/year	tons/year
13.14.			lbs/hour	lbs/hour	tons/year	tons/year
13.15.			lbs/hour	lbs/hour	tons/year	tons/year
4.	Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	ation Necessary to	Understanding the Emissi	on Rates Provided Above	· ·	Y
Attach ti	Attach the Basis of Determination or Calculations for each Emission Rate provided above.	lations for each Emiss	ion Rate provided above.			



Form AQM-5 Page 5 of 8

		Emissions Info	Emissions Information for Fourth Emission Point/Stack	mission Point/Stac	-YI	
15. I	Emission Point Name:					
16. E	Equipment ID Number for all Process	Ш	quipment and Control Devices Venting Through Emission Point/Stack:	ing Through Emission Poi	int/Stack:	
17.	Pollutant Emissions			-		
If more	If more than 15 pollutants are emitted at this Emission		Point/Stack, attach additional copies of this page as needed.	this page as needed.		
	Pollutant Name (Specify VOCs and HAPs Individually in 17.10 through 17.18)	CAS Number (Not required for 17.1 through 17.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Fmissions
17.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
17.2.	PM <sub>10</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.3.	PM <sub>2.5</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.4.	Sulfur Oxides (SO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
17.5.	Nitrogen Oxides (NO <sub>X</sub> )		lbs/hour	lbs/hour	tons/year	tons/year
17.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
17.7.	Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
17.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
17.9.	CO <sub>2</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.10.	· CO <sub>2e</sub>		lbs/hour	lbs/hour	tons/year	tons/year
17.11.			lbs/hour	lbs/hour	tons/year	tons/year
17.12.			lbs/hour	lbs/hour	tons/year	tons/year
17.13.			lbs/hour	lbs/hour	tons/year	tons/year
17.14.			lbs/hour	lbs/hour	tons/year	tons/year
17.15.			lbs/hour	lbs/hour	tons/year	tons/year



## Application to Construct, Operate, or Modify DNREC – Division of Air Quality Stationary Sources)

Form AQM-5 Page 6 of 8

# **Emissions Information for Fourth Emission Point/Stack**

Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above; 8

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

If there are more than four Emission Points/Stacks, attach additional copies of this form as needed.

			Annual Potential to Emit (PTE)	tons/year	tons/year	tons/year	tons/year	tons/year	tons/year	2.65 tons/year	2.17 tons/year	tons/year	tons/year	tons/year
ssions		as needed.	Maximum Controlled Emission Rate at Design Capacity	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	0.18 lbs/hour	0.15 lbs/hour	lbs/hour	lbs/hour	lbs/hour
Overall Process Emissions		emitted from this Process, attach additional copies of this page as needed.	Maximum Uncontrolled Emission Rate at Design Capacity	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	lbs/hour	1.82 lbs/hour	1.49 lbs/hour	lbs/hour	lbs/hour	lbs/hour
)		this Process, attach a	CAS Number (Not required for 19.1 through 19.10)											
	Pollutant Emissions	If more than 15 pollutants are emitted from	Pollutant Name (Specify VOCs and HAPs Individually in 19.10 through 19.18)	Particulate Matter (PM)	PM <sub>10</sub>	PM <sub>2.5</sub>	Sulfur Oxides (SO <sub>X</sub> )	Nitrogen Oxides (NO <sub>X</sub> )	Carbon Monoxide (CO)	Total Volatile Organic Compounds (VOCs)	Total Hazardous Air Pollutants (HAPs)	CO <sub>2</sub>	CO <sub>2e</sub>	
	19.	If more		19.1.	19.2.	19.3.	19.4.	19.5.	19.6.	19.7.	19.8.	19.9.	19.10.	19.12.

tons/year

Emissions

Requested

Permitted Annual tons/year tons/year tons/year tons/year tons/year tons/year

tons/year

tons/year

217 tons/year

.265 tons/year



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)	Overall Process Emissions	sions		
19.13.	lbs/hour	lbs/hour	tons/year	tons/year
19.14.	lbs/hour	lbs/hour	tons/year	tons/year
19.15.	lbs/hour	lbs/hour	tons/year	tons/year
20. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:	Understanding the Emission	n Rates Provided Above:		
Attach the Basis of Determination or Calculations for each Emission Rate provided above.	sion Rate provided above.			
Minor	Minor New Source Review Information	nformation		
21. Does the Process Have the Potential to Emit Mor	Emit More Than Five Tons Per Year of Any Pollutant?	ľ	] YES ⊠ NO	
22. Is the Source New or Existing? See Question 11 of AQM-1	EXISTING			
If the Process has the Potential to Emit more than five tons per year of any pollutant, and is a New Source, a Control Technology Analysis pursuant to Regulation No. 1125 Section 4 must be conducted and attached to this application.	year of any pollutant, and is a Nev ion.	w Source, a Control Technolo	gy Analysis pursuant to F	Regulation No.
Major	Major New Source Review Information	nformation		
23. Does the Process Have the Potential to Emit Mor	Emit More Than the Significance Level for Any Pollutant? (Check All That Apply)	vel for Any Pollutant? (Ch	eck All That Apply)	
<ul> <li>□ Greater Than 25 Tons Per Year of Particulate Matter (PM)</li> <li>□ Greater Than 15 Tons Per Year of PM<sub>10</sub></li> <li>□ Greater Than 10 Tons Per Year of PM<sub>12</sub></li> <li>□ Greater Than 40 Tons Per Year of Sulfur Dioxide(SO<sub>2</sub>)</li> <li>□ Greater Than 25 Tons Per Year of Nitrogen Oxides (NO<sub>x</sub>) in New Castle and Kent County</li> <li>□ Greater Than 100 Tons Per Year of Nitrogen Oxides (NO<sub>x</sub>) in Sussex County</li> <li>□ Greater Than 100 Tons Per Year of Total Volatile Organic Compounds (VOCs) in New Castle and Kent County</li> <li>□ Greater Than 25 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex County</li> <li>□ Greater Than 75,000 Tons Per Year of Equivalent Carbon Dioxide (CO<sub>2e</sub>)</li> </ul>	articulate Matter (PM)  M <sub>1.5</sub> M <sub>2.5</sub> ulfur Dioxide(SO <sub>2</sub> )  itrogen Oxides (NO <sub>x</sub> ) in New Castle a litrogen Oxides (NO <sub>x</sub> ) in Sussex Coucarbon Monoxide (CO)  otal Volatile Organic Compounds (VC otal Volatile Organic Compounds (VC of Equivalent Carbon Dioxide (CO <sub>2e</sub> )	and Kent County unty OCs) in New Castle and K OCs) in Sussex County	ent County	



Form AQM-5 Page 8 of 8 If the Process has the Potential to Emit greater than any of the amounts listed above 7 DE Admin. Code 1125 Sections 2 and/or 3 apply. Contact the Department at (302) 323-4542 or (302) 739-9402 for additional information □ YES ⊠ NO Additional Information Is There Any Additional Information Pertinent to this Application? If YES, complete the rest of Question 24. 24.1. Describe:

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Maximum Emi	ssions Calculat	ions, SD	Maximum Emissions Calculations, SDMicro - Updated 11/10/	11/10/15, Revi	15, Reviewed 5/17/2016				
Run rate <sup>(1)</sup>		1.5	1.5 kg/hr						
Run Time <sup>(2)</sup>		10.0	10.0 hr/day						
Solvent Used (3)		15	15 kg/day						
Operating Days/yr (4)	(4)	292	292 days/yr						
Solvent Spray Dried	-	4380	4380 kg/yr						
Operat	Operating Hours	2,920 hr/yr	hr/yr					One Solvent at 100%	700%
			nysy minimixely	Maximum lh/hr	Maximim tons (vest	Maximixely		Tily and an inchination	Maximum lb/hr
3,	Solvent Mix	%	exhausted	exhausted	exhausted	After Carbon Beds	%	exhausted	carbon beds
	Ethanol	17.0%	744.6	0.561	0.819	0.0561	100%	4380	0.330
	Methanol	35.0%	1533	1.155	1.686	0.1155	100%	4380	0.330
	IPA	1.0%	43.8	0.033	0.048	0.0033	100%	4380	0.330
	Ethy Acetate	1.0%	43.8	0.033	0.048	0.0033	100%	4380	0.330
Met	Methylene Chloride	10.0%	438	0:330	0.482	0.033	100%	4380	0.330
	THF	1.0%	43.8	0.033	0.048	0.0033	100%	4380	0.330
	Acetone	35.0%	1533	1.155	1.686	0.1155	100%	4380	0.330
		100%	4380	3.300	4.818				
				*1  kg = 2.2  lb					
NOTES									
(1) Bas	ed on equipment d	esign, the n	(1) Based on equipment design, the max run rate cannot exceed 1.5	kceed 1.5 kg/hr					
(2) The	equipment runs in	batches, m	(2) The equipment runs in batches, max 6 batches per day. In between batches the time for	in between batches	s the time for				
disasse	mbly, cleaning, dry	ing and assu	disassembly, cleaning, drying and assembly will take at least 14 hour	it 14 hours. The ma	s. The max running time per				
batch p	batch per day is thus 24h minus 14 hours = 10 hours	minus 14 hc	ours = 10 hours						
(3) This	(3) This is total maximum Kg		= solvent + solids. To be conservative,		consider it all solvent and do not				
adjust	adjust out the solids weight.	ht.							
(4) App	roximately 20% of	the time th	(4) Approximately 20% of the time throughout the year between batches, the dryer is also not	tween batches, the	dryer is also not				
runnin	g because the spra	/ dried mate	running because the spray dried material needs to be characterized for particle size, particle size	acterized for particle	e size, particle size				
distrib	ıtion, density, solv∈	ent content	distribution, density, solvent content and morphology. The max running days is thus calculated as	max running days i	is thus calculated as				
follows	follows: (365 days)*(100%-20%)=292 days	5-20%)=292	days						

20160517\_SD micro Emission Calculation.xlsx

					0±0=//=/0 =0::::::/0=/0:				
Run rate (1)	1)	Н	1 kg/hr						
Run Time (2)	(2)	3.0	3.0 hr/day						
Solvent Used (3)	sed <sup>(3)</sup>	m	3 kg/day						
Operating	Operating Days/yr. <sup>(4)</sup>	182.5	182.5 days/yr						
Solvent S	Solvent Spray Dried	547.5 kg/yr	kg/yr						
	Operating Hours	548	548 hr/yr					One Solvent at 100%	100%
					Maximum	Maximum			Maximum lb/hr
			Maximum kg/yr	Maximum lb/hr	tons/year	tons/year After		Maximum kg/yr	exhausted after
	Solvent Mix	%	exhausted	exhausted	exhausted	Carbon Beds	%	exhausted	carbon beds
	Ethanol	17.0%	93.075	0.374	0.102	0.0102	100%	547.5	0.220
	Methanol	35.0%	191.625	0.770	0.211	0.0211	100%	547.5	0.220
	IPA	1.0%	5.475	0.022	0.006	900000	100%	547.5	0.220
	Ethy Acetate	1.0%	5.475	0.022	900.0	0.0006	100%	547.5	0.220
	Methylene Chloride	10.0%	54.75	0.220	0.060	0.0060	100%	547.5	0.220
	THF	1.0%	5.475	0.022	900.0	9000:0	100%	547.5	0.220
	Acetone	35.0%	191.625	0.770	0.211	0.0211	100%	547.5	0.220
		100%	547.5	2.200	0.602				
				*1 kg = 2.2 lb					
	NOTES:								
	(1) Based on equipment design, the max run rate cannot exceed 1 kg/hr	lesign, the m	ax run rate cannot exc	eed 1 kg/hr					
	(2) The equipment runs in batches, typiclly we run 2 batches a day, less than 1.5 hours per batch	ı batches, tyμ	oiclly we run 2 batches	a day, less than 1.5	hours per batch				
	(3) This is total maximum Kg = solvent + solids. To be conservativ	Kg = solvent	t + solids. To be conse	rvative, consider it	e, consider it all solvent and do				
	not adjust out the solids weight.	weight.						8	
	(4) In a typical year, the spray drier is operated less than 50% of the days throughout the year	pray drier is o	operated less than 50%	6 of the days through	shout the year				

## Summary

SD Micro	- 1	er W		Potential To Emit		Expecter	Expected Emission	Permit	Permit Limits
<u>Pollutant</u>	V@C?	HAP?	Maximum Uncontrolled Emission Rate	Maximum Controlled Emission Rate (Mixture)	Annual Potential To Emit (PTE) (tons/yr) <sup>(1),(2)</sup>	Expected Annual Uncontrolled Emissions (tons/yr)	Expected Annual Controlled Emissions (tons/vr)(i)	Emissions (Ib/hr) after Carbon Beds	Emissions as a 12 month rolling period (TPY)
Ethanol	Yes	No	0.561	0.056	0.819	0.102	0.010	0.33	0.082
Methanol	Yes	Yes	1.155	0.116	1.686	0.211	0.021	0.33	69 0
IPA	Yes	No	0.033	0.003	0.048	0.006	0.001	0.33	0.00
Ethyl Acetate	Yes	$N_0$	0.033	0.003	0.048	0.006	0.001	0.33	0.00
Methylene Chloride	No	Yes	0.330	0.033	0.482	0.060	90000	0.33	0.048
Tetrahydrofuran	Yes	No	0.033	0.003	0.048	9000	0.001	0.33	0.005
Acetone	No	No	1.155	0.116	1.686	0.211	0.021	0.33	0.169
VOC	6 = 5		1.82	0.18	2.65	0.33	0.03	NA	0.265
HAP			1.49	0.15	2.17	0.27	0.03	NA	0.217
Notes:						8			
(1) The controlled emissions assume a carbon adsorption control efficiency of 90%. There are two carbon canisters operating in series, so the actual control efficiency will be greater than 90%.	ions assu rol efficie	me a carb	on adsorption cont	rol efficiency of 90%.	)%. There are tw	vo carbon canister	s operating in		
(2) Acetone, as defined by the US EPA, is neither a VOC nor a HAP, and the totals are not included in the VOC or HAP totals	by the US	EPA, is r	leither a VOC nor	a HAP, and the tot	als are not includ	led in the VOC or	- HAP totals		

## MP-1 Fluid Bed Dryer

Form AQM-3.1 Page 1 of 6

## Generic Process Equipment Application If you are using this form electronically, press F1 at any time for help

	you are		,,,,			
		General Infor	mation			
1.	Facility Name: Hercul	les / Ashland Research Cente	er .			
2.		::MP-1 Fluid Bed Dryer				
3.	granulating and coati	otion of Equipment or Process: ing for pharmaceutical resea adsorber beds in series.				
4.	Manufacturer: Aeroma	atic				
5.	Model:					
6.	Serial Number: 97900	721				
-						
		Raw Material Inf	iormation			
7.	Raw Materials Used in	Process				
If the	re are more than four Raw Ma	aterials used, attach additional copie	es of this page as needed.			
	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?		
7.1.	Active pharmaceuticals and excipients	N/A	Varies	☐ YES ⊠ NO		
7.2.	Ethanol	64-17-5	1917 kg/yr average	☐ YES ☐ NO		
7.3.	Methanol	67-56-1	0 kg/yr average	☐ YES ☐ NO		
7.4.	Acetone	67-64-1	128 kg/yr average	☐ YES 🖾 NO		
	Attach a copy of a <u>ll</u> calculations made to support the data in the table above.  Attach a Material Safety Data Sheet (MSDS) for <u>each</u> Raw Material used.					
		Products Produced	Information			
8. ·	Products Produced					
If ther	e are more than four Product	ts Produced, attach additional copie	es of this page as needed.			
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?		
8.1.	R&D pharmaceuticals	N/A	Various	☐ YES 🖾 NO		
8.2.				☐ YES ☐ NO		
8.3.				☐ YES ☐ NO		
8.4.				☐ YES ☐ NO		

Form AQM-3.1 Page 1a of 6

## **Generic Process Equipment Application**

If you are using this form electronically, press F1 at any time for help

	General Information
1.	Facility Name: Hercules / Ashland Research Center
2.	Equipment ID Number: MP-1 Fluid Bed Dryer
3.	Provide a brief description of Equipment or Process: Small fluid bed processor for spray drying, granulating and coating for pharmaceutical research. The uncontrolled emissions are vented through two carbon adsorber beds in series.
4.	Manufacturer: Aeromatic
5.	Model:
6.	Serial Number: 97900721

	Raw Material	<u>Information</u>		
7. Raw Materials Used i	n Process			
If there are more than four Raw N	laterials used, attach additio	nal copies of this page as needed.		
Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?	
7.1. Isopropanol	67-63-0	511 kg/yr average	YES X NO	
7.2. Ethyl Acetate	7.2. Ethyl Acetate 141-78-6 0 kg/yr average YES X NO			
7.3. Methylene Chloride	75-09-2	0 kg/yr average	YES X NO	
7.4. Tetrahydrofuran	109-99-9	0 kg/yr average	YES X NO	

		Products Products	duced Information	
8.	Products Produced			
If the	are are more than four Produ	ucts Produced, attach addition	nal copies of this page as needed.	
	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.	is:			☐YES ☐NO
8.2.	N			☐YES ☐NO



Form AQM-3.1 Page 2 of 6

Attach a copy of a <u>ll</u> calculations made to support the data in the table above. Attach a Material Safety Data Sheet (MSDS) for <u>each</u> Product Produced.	Products Produced Information	
	Attach a copy of a <u>ll</u> calculations made to support the data in the table above. Attach a Material Safety Data Sheet (MSDS) for <u>each</u> Product Produced.	

Attac	h a Material Safety Data She	eet (MSDS) for <u>each</u> Product Pr	roduced.	
·				
		Byproducts Gen	erated Information	
9.	Byproducts Generated	t		
If ther	re are more than four Byprod	ducts Generated, attach additi		eeded.
	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?
9.1.				⊠ YES □ NO
9.2.				☐ YES ☐ NO
9.3.				☐ YES ☐ NO
9.4.				☐ YES ☐ NO
		made to support the data in the et (MSDS) for <u>each</u> Byproduct		
		General I	nformation	
11.	cannot exceed 1 kg/h	anufacturer Specifications		eters for Equipment or
Attach	the Manufacturer's Specific	cation Sheet(s) for the equipm	ent or process.	
		Control Device	ce Information	
12.	ls an Air Pollution Contr	rol Device Used?	☑ YES ☐ NO	
If an A	Air Pollution Control Dev	vice is used, complete the	rest of Question 12. If no	ot, proceed to Question 13.
	Is Knockout Used?		☐ YES ⊠ NO	
		and attach it to this application		
12.2.	Is a Settling Chamber U	Jsed?	☐ YES ☐ NO	
If YES,	, complete Form AQM-4.10 a	and attach it to this application	lij	
12.3.	Is an Inertial or Cyclone	e Collector Used?	☐ YES ☒ NO	
If YES,	, complete Form AQM-4.5 an	nd attach it to this application.		
	Is a Fabric Collector or		☐ YES ☐ NO	
If YES,		nd attach it to this application.		
12.5.	Is a Venturi Scrubber U	Jsed?	☐ YES 図 NO	



Form AQM-3.1 Page 3 of 6

Control Device Information	
If YES, complete Form AQM-4.8 and attach it to this application.	
12.6. Is an Electrostatic Precipitator Used? ☐ YES ☒ NO	
If YES, complete Form AQM-4.7 and attach it to this application.	
12.7. Is Adsorption Equipment Used?  ☐ YES ☐ NO	
If YES, complete Form AQM-4.2 and attach it to this application.	
12.8. Is a Scrubber Used? ☐ YES ☒ NO	
If YES, complete Form AQM-4.4 and attach it to this application.	
12.9. Is a Thermal Oxidizer or Afterburner Used? ☐ YES ☒ NO	
If YES, complete Form AQM-4.1 and attach it to this application.	
12.10. Is a Flare Used? ☐ YES ☒ NO	
If YES, complete Form AQM-4.3 and attach it to this application.	
12.11. Is Any Other Control Device Used? ☐ YES ☒ NO	
If YES, attach a copy of the control device Manufacturer's Specification Sheet(s).	
If any other control device is used, complete the rest of Question 12. If not, proceed to Question 13.	
12.12. Describe Control Device:	
12.13. Pollutants Controlled:   VOCs HAPs PM PM <sub>10</sub> PM <sub>2.5</sub> NO <sub>X</sub> SO <sub>X</sub> Metals Other (Specify):	
12.14. Control Device Manufacturer:	
12.15. Control Device Model:	
12.16. Control Device Serial Number:	
12.17. Control Device Design Capacity:	
12.18. Control Device Removal or Destruction Efficiency:	
Stack Information	
<ul> <li>How Does the Process Equipment Vent:     (check all that apply)     □ Directly to the Atmosphere     ☑ Through a Control Device Covered by Forms AQM-4.1 through 4.12     □ Through Another Control Device Described on This Form</li> </ul>	
If any of the process equipment vents directly to the atmosphere or through another control device described on this form, proceed to Question 14. If the process equipment vents through a control device, provide the stack parameters on the control device form and proceed to Question 18.	d
14. Number of Air Contaminant Emission Points: 1	
If there are more than three Emission Points, attach additional copies of this page as needed.	
For the first Emission Point	
15. Emission Point Name: MP-1	
15.1. Stack Height Above Grade: 10 feet	



Form AQM-3.1 Page 4 of 6

Stack Information
15.2. Stack Exit Diameter: 0.333 feet (Provide Stack Dimensions If Rectangular Stack)
15.3. Is a Stack Cap Present? ☐ YES ☒ NO
15.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting (check all that apply) ☐ Other (Specify):
15.5. Stack Exit Gas Temperature: 20 °C
15.6. Stack Exit Gas Flow Rate: 29.7 ACFM
15.7. Distance to Nearest Property Line: 362 feet
15.8. Describe Nearest Obstruction: Building 8162
15.9. Height of Nearest Obstruction: 32 feet
15.10. Distance to Nearest Obstruction: about 10 feet
15.11. Are Stack Sampling Ports Provided? ☐ YES ☐ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.
16. Emission Point Name:
16.1. Stack Height Above Grade: feet
16.2. Stack Exit Diameter: feet (Provide Stack Dimensions If Rectangular Stack)
16.3. Is a Stack Cap Present?
16.4. Stack Configuration:  Vertical  Horizontal Downward-Venting (check all that apply) Other (Specify):
16.5. Stack Exit Gas Temperature: °F
16.6. Stack Exit Gas Flow Rate: ACFM
16.7. Distance to Nearest Property Line: feet
16.8. Describe Nearest Obstruction:
16.9. Height of Nearest Obstruction: feet
16.10. Distance to Nearest Obstruction: feet
16.11. Are Stack Sampling Ports Provided?
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.
17. Emission Point Name:
17.1. Stack Height Above Grade: feet
17.2. Stack Exit Diameter: feet (Provide Stack Dimensions If Rectangular Stack)
17.3. Is a Stack Cap Present?
17.4. Stack Configuration: Vertical Horizontal Downward-Venting (check all that apply) Other (Specify):
17.5. Stack Exit Gas Temperature: °F
17.6. Stack Exit Gas Flow Rate: ACFM
17.7. Distance to Nearest Property Line: feet



Form AQM-3.1 Page 5 of 6

Stack Information	
17.8. Describe Nearest Obstruction:	
17.9. Height of Nearest Obstruction: feet	
17.10. Distance to Nearest Obstruction: feet	
17.11. Are Stack Sampling Ports Provided?	
Monitoring Information	
18. Will Emissions Data be Recorded by a Continuous Emission Monitoring ☐ YES ☒ NO System?	
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.1. Pollutants Monitored: VOCs HAPs PM PM <sub>10</sub> PM <sub>2.5</sub> NO <sub>X</sub> SO <sub>X</sub> Metals Other (Specify):	
18.2. Describe the Continuous Emission Monitoring System:	
18.3. Manufacturer:	
18.4. Model:	
18.5. Serial Number:	
18.6. Will Multiple Emission Units Be Monitored at the Same Point?   YES NO	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.7. Emission Units Monitored:	
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At Any Time?	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.9. Emission Units Emitting Simultaneously:	
Voluntary Emission Limitation Request Information	
19. Are You Requesting Any <u>Voluntary Emission Limitations</u> to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?  ☐ YES ☒ NO	
If YES, complete the rest of Question 19. If NO, proceed to Question 20.	
19.1. Describe Any Requested Emission Limitations:	
Voluntary Operating Limitation Request Information	
20. Are You Requesting Any Voluntary Operating Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, ☐ YES ☒ NO etc.?	

Form AQM-3.1 Page 6 of 6

	Voluntary Operating Limitation Request Information
If YES	S, complete the rest of Question 20. If NO, proceed to Question 21.
20.1.	Describe Any Requested Operating Limitations:
1	
	Additional Information
21.	Additional Information  Is There Any Additional Information Pertinent to this Application? ☐ YES ☒ NO
	Is There Any Additional Information Pertinent to this Application?
If YES	Is There Any Additional Information Pertinent to this Application?   YES  NO  S, complete the rest of Question 21.